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A Randomized, Double Blind, Placebo Controlled, Single Centric, 2 Arm Clinical Trial to Assess the Efficacy and Safety of Amrith Noni D Plus in Patients with Type II Diabetes Mellitus who are on OHA.

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KEYWORDS

Morinda citrifolia L, Amrith Noni D Plus, Type II Diabetes Mellitus, Placebo, Clinical Study, Oral Route.

ABSTRACT:

The number of people with Diabetes Mellitus is rapidly increasing in the current generation. There are several medications researched and manufactured by the pharmaceutical industry but almost all of them have been reported to have some side effects or the other. Many researchers and doctors are trying to find natural alternatives that can keep the sugar levels under control. One such medicinally important plant is *Morinda citrifolia L.,* commonly known as Noni. The primary objective of this study is to evaluate the efficacy of Amrith Noni D Plus in patients with Type II Diabetes Mellitus who are on Oral Hypoglycaemic Agent with that of a placebo. Apart from that the safety, tolerability of the same was also assessed. The study's results show that there was no adverse effect after 24 weeks and there was a significant change in the laboratory tests conducted.

1. Introduction

A significant portion of the population now suffers from obesity and diabetes as a result of changes in modern living and poor eating habits during the past 20 years (Boutari and Mantzoros 2022). Several synthetic anti-diabetic medications are widely available on the market to meet the demands of these individuals but long-term usage of these medications has led to a number of harmful adverse effects. In both industrialized and emerging nations, diabetes mellitus is becoming a more serious public health issue (Chaudhury et al. 2017). As per the August 2011 World Health Organization study, 346 million individuals globally suffer from diabetes. Furthermore, it's predicted that complications from diabetes claimed the lives of 3.4 million individuals in 2004. By 2030, this number is probably going to quadruple if nothing urgent is done. Both forms of diabetes eventually cause major health issues such as neuropathy, retinopathy, nephropathy, dyslipidemia, and cardiovascular disorders (Lin et al. 2020). Currently, the most commonly used medications include insulin, α-glucosidase inhibitors, incretin agonists, dipeptidyl peptidase-4 inhibitors, biguanides, thiazolidinediones, and insulin secretagogues (sulfonylureas, meglitinides) (Lorenzati et al. 2010). Even while insulin therapy and oral hypoglycemic medications can control diabetes's early-onset problems, many people experience severe late-onset complications (Zuo et al. 2021). Additionally, the unpleasant side effects of the present medications' clinical usage include severe hypoglycemia, lactic acidosis, peripheral edema, and stomach discomfort (Stroup and Gray 2018). As a result, efforts to find novel antidiabetic drugs with improved efficacy and fewer adverse effects have continued. Because of growing concerns about the use of synthetic chemicals, natural goods and plant-based medications are becoming more and more important as sources of antidiabetics (Dahlén et al. 2022), (Tran et al. 2020). Historically, medicinal plants have been a valuable resource for discovering novel treatments for illnesses affecting human health (Petrovska 2012). Numerous herbs have historically been

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suggested as treatments for diabetes. Numerous researchers have also documented the antidiabetic properties of a wide variety of plants. One aspect of human health that is frequently underestimated is blood sugar (Przeor 2022). It has been demonstrated that elevated blood sugar levels over an extended length of time have the potential to progress to diabetes. Diabetes impairs the body's capacity to create or utilize insulin, a hormone that is necessary for the body to convert glucose (sugar) into energy (González et al. 2023).

In this case, eating specific fruits and herbs appears to help with glycemic management by producing a hypoglycemic impact in those with diabetes (Yeh et al. 2003). *Morinda citrifolia* L., better known as noni fruit juice (NJ), is a prevalent complementary medicine used to treat a variety of ailments, including atherosclerosis and diabetes (Chanthira Kumar et al. 2022). Despite its long history of use, there is little scientific proof of its nutritional and therapeutic benefits for people (Pan et al. 2014). No evidence has been released to support its lipid-lowering effects, despite reports that it inhibits an enzyme involved in the manufacture of cholesterol (Mirzai and Laffin 2023). The purpose of the study is to look into the safety of Noni Juice in diabetic patients as well as its positive effects on endogenous antioxidant activity, plasma lipid profile, and glycaemic management (Bhowmik et al. 2018).

Noni is one of the most significant medicinal herbs used by societies all over the world in their long-standing healing traditions. Different tropical communities have different uses for different sections of the plant, as well as different medical applications. Societies also differ in the plant's significance. However, the plant's greatest significant application may be as a medicinal use due to its widespread usage (West et al. 2018). Healers frequently combined Noni with other herbs to make remedies. Herbalists frequently mixed exact amounts and mixes of herbs to effect more thorough remedies for intricate issues. The most common way to eat Noni is in juice. Whole fruit powder (with seeds) and seedless fruit powder are examples of additional edible goods (Hussain 2011). Noni is thought to be beneficial and safe when used in conjunction with more established, contemporary medical therapy, even in the absence of established scientific findings about its therapeutic effects (Samarasinghe et al. 2024). Studies have discovered anti-diabetic compounds in Noni roots but not in noni fruits, which have demonstrated the strongest anti-diabetic benefits as previously mentioned (Fadlilah et al. 2024). In comparison to insulin-treated cells, alizarin-2-methyl ether, rubiadin-1-methyl ether, and 1,2 dimethoxyanthraquinone extracted from *Morinda citrifolia* L., roots enhanced adipocyte development in 3T3-L1 mouse adipocytes, suggesting possible anti-diabetic effects. Male mice treated with streptozotocin showed reduced blood glucose levels in response to two anthroquinones extracted from *M. citrifolia* roots: lucidin 3-O-β-d-primeveroside and morindone-6-O-β-d-primeveroside. Similarly, ursolic acid, lirioresinol B, lirioresinol B dimethyl ether, and episesamin 2,6-dicatechol that were isolated from dried powder of *Morinda citrifolia* (plant parts unknown) improved the uptake of glucose by 3T3-L1 adipocytes (Anantharaj et al. 2017). *Morinda citrifolia* (Noni) reduces blood glucose levels because it contains proxeronine, flavonoids, scopoletin, terpens, anthraquinones which has a hypoglycemic effect. Noni fruit and juice have been shown in studies to have anti-diabetic effects. Also, anti-diabetic herbs like Salacia reticulata (sapthachakra), syzygium jambolana (jambu), gymnema sylvestre (madhunashini) and other powerful herbs present in Amrith noni D Plus helps to bring down the sugar levels effectively. Additionally, research has shown that noni juice can effectively improve insulin sensitivity, glucose tolerance, and fasting glucose levels (Algenstaedt et al. 2018). Nowadays, doctors not only permit their patients to take noni supplements, but in certain situations, they are even writing prescriptions for it. Patients in Hawaii with a variety of cancers are receiving it from cancer specialists (Matriz et al. 2024). Impressive anecdotal accounts are emerging from these treatments. In the cases of diabetes and cancer, anecdotal accounts of pain alleviation and symptom reduction are remarkable (Campo 2006). Various formulations of insulin are available in the market currently. These medications do, however, differ in their pharmacokinetics, which affects how long they take to start working and how long they stay active after injection (Bolli et al. 2022). Furthermore, problems or adverse effects from the current medicine are possible. A medicine's or device's manufacturer, regulator, and medical specialists must assess the advantages and disadvantages of the product. This occasionally entails weighing the advantages and disadvantages for the broader public (Ryan et al. 2014).

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At times, it could entail weighing the advantages and disadvantages for a certain patient. So, there is a need for solution that would control the blood sugar level of the human being and thus fighting diabetes in a simpler and effective manner (Xiao et al. 2017). The solution needs to be through oral medication with minimal to zero side effects. The present disclosure provides a simple and effective way of preparation of an herbal based composition that is produced using natural and synthetic ingredients (Matriz et al. 2024). In our clinical trial purpose, we were ready to screen and recruit 30 minimum number of participants for 6 months duration of the trial to know about the Amrith Noni D Plus drug's long-term efficacy. According to some research articles the noni fruit shows anti-diabetic effect on human after 25 days regular basis consumption. Hence, we are known to the long-term drug efficacy. The purpose of this study was to examine the efficacy and safety of Amrith Noni D Plus (Test product), which was manufactured by Valyou Products Private Limited, in comparison to a placebo in participants who had been diagnosed with Type II diabetes. The investigation was done in a single-centric, randomized, double-blind, and placebo-controlled manner.

2. Methods

Selection and screening of patient

This randomized, placebo-controlled, double-blind study consisting of 32 adult patients of either gender of type 2 diabetes mellitus out of which 32 subjects were screened and 30 enrolled into the study and 30 completed the study. Signed Informed consent form was obtained from every subject, demographic data, physical examination with vital signs, medical history, treatment history and co-morbid conditions including any active, chronic, recurrent or latent infections were captured. Every participant had a comprehensive physical assessment. The data collected included information on demographics, vital signs, medical history, treatment history, and any co-morbid conditions, if applicable. During the screening visit, laboratory tests were undertaken, including complete blood count (CBC), serum glutamic pyruvic transaminase (SGPT), serum glutamic oxaloacetic transaminase (SGOT), serum creatinine, uric acid, potassium, C-reactive protein (CRP), glycated hemoglobin (HbA1c), fasting blood sugar (FBS), 2-hour postprandial (PP) glucose, and lipid profile. Female respondents underwent a urine pregnancy test. The screening visit, which occurred within a range of 2 days, was followed by the baseline visit on Day 0. During the baseline visit, individuals who met the inclusion/exclusion criteria were enrolled in the study and their vital signs were recorded. During this visit, the participants were randomly assigned to either Group 1 (receiving Amrith Noni D Plus) or Group 2 (receiving Placebo).

Method of assigning patients to treatment groups

For the purpose of the study, 30 adults who had been diagnosed with Type II diabetes and were taking OHA were recruited. Beginning on the day when the subjects were randomly assigned, their involvement in the study lasted for a period of 24 weeks. The only time they were allowed to participate in the study was after they fulfilled the inclusion and exclusion criteria.

Each group had:

Group 1: 15 subjects will receive the test product and OHA;

Group 2: 15 subjects will receive placebo and OHA.

Treatments administered

After the subjects were enrolled into the study, they were asked to come on Week 12 (Visit 3) and Week 24 (Visit 4) after randomization. During visit 2, they were dispensed with study products (either active or placebo). In this visit they were instructed about how to take the IP. The subjects in Group 1 (on Amrith Noni D Plus) were asked to take 5ml (First 3 days), 10ml (next 3 days) and 15ml syrup to be taken orally twice daily on empty stomach in the morning and 1 hr before dinner in the evening till the end of the study along with OHA. All subjects receiving Group 2 (on placebo) were asked to take 5ml (First 3 days), 10ml (next 3 days) and 15 ml syrup to be taken orally twice daily on empty stomach in the morning and 1 hr before dinner in the evening till the end of the study along with OHA. Concomitant medication, if any, were recorded in the respective forms.

Comprehensive health profile

Blood sampling (CBC, SGPT, SGOT, serum creatinine, Uric acid, Potassium, CRP, HbA1c, FBS, 2 Hour PPBS and Lipid profile) for hematology and

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biochemistry were performed using kits. Urine pregnancy test for female subjects was performed.

3. Results

Noni (*Morinda citrifolia* L.,) is a very popular medicinal plant that has been researched by several scientists for a long time now. Several of them have shown positive results while a few of them could not conclude anything specific. A study by Sabitha et al. found that Noni Juice did not significantly improve glycaemic control, lipid lowering, or antioxidant activity in diabetic patients. The study also ruled out negative effects on organ functions and short-term use (Sabitha et al. 2009). The small sample size and lack of power in detecting significant differences suggest further research is needed (West et al. 2018). Nerurkar et al. in a review have summarized 15 *In-vivo* and *In-vitro* studies investigating the anti-diabetic effects of noni (Nerurkar et al. 2015). In a study by Fernandes et al., long-term Noni treatment helped to prevent the effects of diabetes mellitus on exercise performance until exhaustion and to reduce hyperglycemia. However, given that kidney morphological change was noted, caution must be exercised while utilizing Noni as a therapeutic and nutritional strategy in the treatment of diabetes mellitus. Additionally, they believe that a significant research limitation is that, in contrast to natural disease induction, DM experimental induction does not foster comparable entire organic circumstances (De Oliveira Fernandes et al. 2023). A study by Dafriani et al. had sixteen respondents. A control group and a treatment group were split apart. Eight respondents made up each group. For 10 days, the intervention group was given 150 ml of noni juice once a day. The glucocheck method was used to test for glucose. A capillary on the respondent's fingertips provided the blood. The independent t-test was used to examine the blood glucose results between the intervention group and the control group. The intervention group's average blood glucose level was 199.88 mg/dl, compared to 326.25 mg/dl in the control group. There was a significant change in the mean blood glucose test results between the intervention group and the control group, with a p-value of 0.003 ($p < 0.05$) (Putri Dafriani et al. 2020).

This study was performed to know whether the study product will be effective and safe for the treatment of Type II DM. Adult subjects who were having Type II DM were screened for this study from the outpatient department of the trial site. This study was a randomized, placebo-controlled, double-blind trial including 32 adult patients with Type 2 Diabetes Mellitus. Out of the 32 people screened, 30 were recruited in the study, and all 30 successfully finished and executed. Every subject provided informed consent, and their demographic data, vital signs, medical history, treatment history, and co-morbid conditions (including any active, chronic, recurrent, or latent infections) were recorded after a physical examination. Each participant underwent a thorough physical evaluation. The collected data encompassed demographics, vital signs, medical history, treatment history, and any co-morbid conditions.

Table 1: Subject Demographics and Baseline Characteristics at Screening Visit:

Parameter/Statistics	Active	Placebo
Age (Years)		
n	15	15
Mean (SD)	53.3(9.63)	51.8(7.64)
Median	56.0	51.0
Min, Max	35,64	40,63
Gender, n (%)		
Female	6(40.0)	6(40.0)
Male	9(60.0)	9(60.0)
Past Medical History		
NO	0(0.0)	0(0.0)
YES	15(100.0)	15(100.0)
Treatment History		
NO	0(0.0)	0(0.0)
YES	15(100.0)	15(100.0)
Co-Morbid Conditions		
NO	0(0.0)	0(0.0)
YES	15(100.0)	15(100.0)
Concomitant Medication		
NO	0(0.0)	0(0.0)
YES	15(100.0)	15(100.0)
HEIGHT		
n	15	15
Mean (SD)	168.8(3.47)	166.9(3.38)
Median	168.0	166.0
Min, Max	165,179	162,172
WEIGHT		
Screening		
n	15	15
Mean (SD)	64.4(5.64)	65.4(7.41)

They were only recruited after a written consent was signed and the inclusion exclusion criteria was met. They were equally randomized into active and placebo group and were asked to administer orally the study product for 24 weeks from the day of randomization. At the end point of the study, it was possible to see a change

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in HbA1c, a positive change in FBS, PPBS, LDL, HDL, TC and lipid profile on subjects on active when compared to placebo from baseline to visit 3 and baseline to visit 4.

HbA1c is an invaluable instrument for effectively treating type 2 diabetes, fulfilling several roles in the areas of diagnosis, monitoring, and prognosis. It is employed as a diagnostic tool for dysglycemia and diabetes, frequently in conjunction with fasting blood glucose and glucose tolerance tests (Flores Poveda et al. 2020). HbA1c readings equal to or greater than 6.5% can be utilized as a means of screening for and diagnosing type 2 diabetes. However, there is ongoing debate on the acceptable thresholds for this purpose (Bernard et al. 2017). Research has demonstrated that HbA1c is somewhat more effective in distinguishing type 2 diabetes than fasting plasma glucose, with respective areas under the curve of 0.97 and 0.92 (Saleh 2019). The levels of HbA1c are notably elevated in individuals with type 2 diabetes in comparison to those without the condition, and there is a strong association between HbA1c levels and fasting blood glucose levels (Shojaei Shad and Haghighi 2018). HbA1c serves as the main instrument for managing and modifying treatment in type 2 diabetes. Additionally, it has a crucial role in predicting problems associated with diabetes (Flores Poveda et al., 2020).

Table. 2. Descriptive Stats for HbA1c

Parameter/Statistics	Visit	Active	Placebo
HbA1c (%)			
n	Screening	15	15
Mean (SD)	Screening	8.8(0.50)	8.7(0.42)
Median	Screening	8.6	8.5
Min, Max	Screening	8.1,9.8	8.2,9.4
n	Visit 3	15	15
Mean (SD)	Visit 3	7.7(0.52)	8.4(0.48)
Median	Visit 3	7.6	8.2
Min, Max	Visit 3	7.1,8.7	7.8,9.4
n	Visit 4	15	15
Mean (SD)	Visit 4	6.2(0.48)	7.8(0.49)
Median	Visit 4	6.0	7.8
Min, Max	Visit 4	5.7,7.4	7.1,8.8

Figure 1 demonstrate that investigational product is more effective than placebo for the management of Type II DM. it is the mean score for the HbA1c changes from screening to visit 3 and visit 4. Mean value on screening for subjects on active was 8.8 for HbA1c. On visit 3 the mean score decreased to 7.7. It was 6.23 on visit 4. Mean value on screening for subjects on placebo was 8.7. On visit 3 the mean scores were 8.41. It was the 7.8 on visit 4.

Figure. 1. The mean score for the HbA1c changes from screening to visit 3 and visit 4.

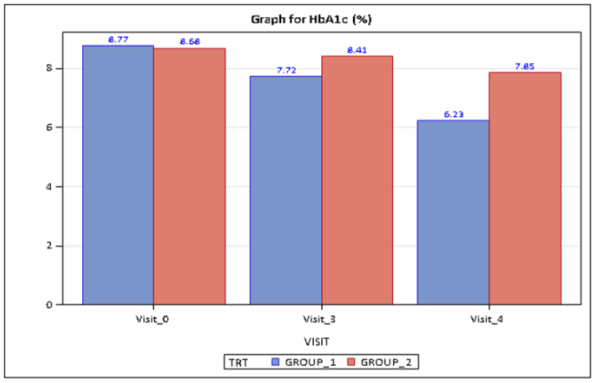

Table. 3. Listing for efficacy analysis of HbA1c – Active

Subject Number	Parameter	Baseline Visit	Visit 3	Visit 4	Improvement Baseline to Visit 3	Improvement Baseline to Visit 4
Subject 01	HbA1c	8.2	7.1	5.9	Yes	Yes
Subject 05	HbA1c	8.1	7.1	6.0	Yes	Yes
Subject 08	HbA1c	8.8	7.6	5.7	Yes	Yes
Subject 09	HbA1c	9.2	8.3	6.1	Yes	Yes
Subject 10	HbA1c	9.4	8.7	7.4	Yes	Yes
Subject 11	HbA1c	8.9	7.2	5.9	Yes	Yes
Subject 12	HbA1c	8.2	7.6	6.0	Yes	Yes
Subject 13	HbA1c	9.8	8.1	6.6	Yes	Yes
Subject 18	HbA1c	8.6	7.2	5.8	Yes	Yes
Subject 19	HbA1c	8.5	7.2	6.0	Yes	Yes
Subject 21	HbA1c	8.6	7.9	6.3	Yes	Yes
Subject 24	HbA1c	8.5	7.4	5.9	Yes	Yes
Subject 25	HbA1c	9.2	8.4	7.0	Yes	Yes
Subject 27	HbA1c	9.2	8.1	6.6	Yes	Yes
Subject 30	HbA1c	8.4	7.9	6.2	Yes	Yes

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Table 4: Listing for efficacy analysis of HbA1c – Placebo

Subject Number	Parameter	Baseline Visit	Visit 3	Visit 4	Improvement Baseline to Visit 3	Improvement Baseline to Visit 4
Subject 02	HbA1c	9.4	8.8	8.1	Yes	Yes
Subject 03	HbA1c	8.9	8.2	7.8	Yes	Yes
Subject 04	HbA1c	8.2	8.1	7.6	Yes	Yes
Subject 06	HbA1c	8.2	8.0	7.2	Yes	Yes
Subject 07	HbA1c	8.9	8.5	7.9	Yes	Yes
Subject 14	HbA1c	9.2	9.4	8.8	No	Yes
Subject 15	HbA1c	8.5	9.1	8.6	No	No
Subject 16	HbA1c	8.4	8.0	7.8	Yes	Yes
Subject 17	HbA1c	8.4	8.1	7.5	Yes	Yes
Subject 20	HbA1c	8.5	8.2	7.7	Yes	Yes
Subject 22	HbA1c	8.6	8.2	7.8	Yes	Yes
Subject 23	HbA1c	9.2	8.8	8.5	Yes	Yes
Subject 26	HbA1c	8.2	7.8	7.1	Yes	Yes
Subject 28	HbA1c	9.2	8.9	7.9	Yes	Yes
Subject 29	HbA1c	8.4	8.0	7.4	Yes	Yes

Table 5: The p-values showed high significance between the treatment groups, with a high probability of p-value <.0001.

Visit	Statistic	t Value	DF	Prob
Baseline to Visit 3	Ancova	-6.22	28	<.0001
Baseline to Visit 4	Ancova	-12.19	28	<.0001

The Ancova method was used to analyze the data, revealing significant variation in both active and placebo scores from baseline to visit 3 and visit 4 within the treatment group. The results suggest a significant difference in HbA1c levels between active and placebo groups.

Table. 6. p value within treatments (Active) for improvement of HbA1c - baseline to visit 3 and baseline to visit 4.

Visit	Statistic	t Value	DF	Prob
Baseline to Visit 3	Paired t test	-11.08	14	<.0001
Baseline to Visit 4	Paired t test	-24.35	14	<.0001

Table. 7. p value within treatments (Placebo) for improvement of HbA1c - baseline to visit 3 and baseline to visit 4.

Visit	Statistic	t Value	DF	Prob
Baseline to Visit 3	Paired t test	-3.34	14	0.0049
Baseline to Visit 4	Paired t test	-8.87	14	<.0001

The p value of all the given variables showed that subjects on active showed a high statistical significance (p value – <0.0001 and <0.0001) when compared to placebo.

Fasting blood glucose (FBG) is essential for the diagnosis and management of type II diabetes. Chauhan et al. (2019) discovered a direct relationship between fasting blood glucose (FBG), glycosylated hemoglobin (HbA1c), and serum cholesterol levels in individuals with diabetes (Chauhan et al. 2019). Holman & Turner (1988) introduced a management approach that involves measuring FBG (fasting blood glucose) levels every 3 months. The goal of this method is to keep glucose levels within the range of 4-6 mmol/l in order to achieve optimal glucose control (Holman and Turner 1988). Nevertheless, Islam (2011) emphasized the drawbacks of exclusively depending on FBG for diagnosis, as certain instances may necessitate postprandial glucose readings (Islam 2011). Tayek et al. (2018) proposed that targeting FBG control is crucial for achieving desired HbA1c levels. They stated that maintaining FBG levels below 100 mg/dl over a period of 2-3 months could result in 70% of patients achieving a HbA1c goal below 7.0%. In addition, they presented a straightforward equation to determine HbA1c using FBG (Tayek 2018). These studies jointly highlight the significance of FBG in diabetes management while recognizing its constraints and the necessity for a thorough evaluation. In this study we have Fasting blood sugar (FBS) is essential for the diagnosis and management of type II diabetes.

Figure. 2. Mean Value of FBS

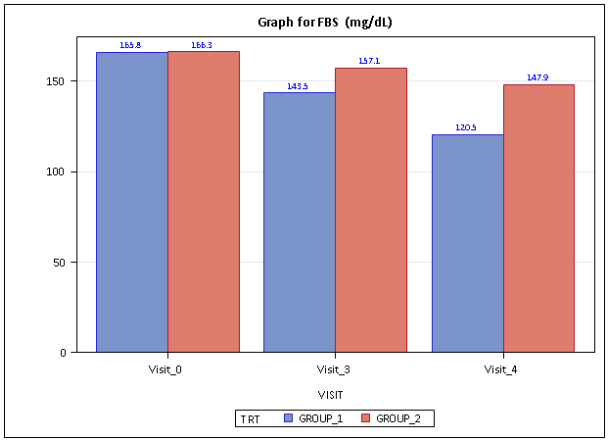

Figure 2 shows the average score of FBS for the active and placebo groups during the study visits. The

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graph indicates that there was a disparity in the prevalence of study product responders between the groups at Visit 3 and Visit 4 compared to the Baseline. The baseline mean value for those on the active treatment was 165.8, while for those on the placebo treatment it was 166.3. During Visit 3, subjects who received the active treatment exhibited a highly significant decrease in FBS levels, with a mean value of 143.5, compared to the placebo group with a mean value of 157.1. Similarly, during Visit 4, individuals on the active treatment showed a highly significant decrease in FBS levels, with a mean value of 120.5, compared to the placebo group with a mean value of 147.9. The minimum score for participants on active was 158.0, while the maximum score was 170.0, according to Table 08. During the third visit in week 12, the FBS score decreased from 158.0 to 130.0, and the maximum score decreased from 170.0 to 155.0. During the fourth visit on week 24, the lowest score of FBS decreased from 158.0 to 110.0, and the highest score decreased from 170.0 to 132.0. The minimum score for FBS (Table 08) among participants on placebo was 158.0, whereas the maximum score was 170.0. During the third visit on week 12, the FBS score decreased from 158.0 to 150.0, and the maximum score decreased from 170.0 to 165.0. During week 24 (visit 4), the minimum score of FBS decreased from 158.0 to 140.0, while the highest score decreased from 170.0 to 158.0.

Table 8: Descriptive Stats

Parameter/Statistics	Visit	Active	Placebo
FBS (mg/dL)			
n	Screening	15	15
Mean (SD)	Screening	165.8(4.09)	166.3(4.27)
Median	Screening	166.0	168.0
Min, Max	Screening	158.0,170.0	158.0,170.0
n	Visit 3	15	15
Mean (SD)	Visit 3	143.5(7.61)	157.1(4.88)
Median	Visit 3	142.0	158.0
Min, Max	Visit 3	130.0,155.0	150.0,165.0
n	Visit 4	15	15
Mean (SD)	Visit 4	120.5(6.60)	147.9(5.85)
Median	Visit 4	120.0	148.0
Min, Max	Visit 4	110.0,132.0	140.0,158.0

Table. 9. p value Between Treatments (Active vs. Placebo) for improvement of FBS - baseline to visit 3 and baseline to visit 4.

Visit	Statistic	t Value	DF	Prob
Baseline to Visit 3	Ancova	-7.76	28	<.0001
Baseline to Visit 4	Ancova	-11.73	28	<.0001

The study found that active subjects showed significantly higher p-values at week 12 (visit 3) and week 24 (visit 4) compared to placebo subjects (Table 09). The p-value data indicates the degree of variance seen between the baseline visit and visits 3 and 4 in both the active and placebo groups within the treatment group.

Table.10. p value within Treatments (Active) for improvement of FBS - baseline to visit 3 and baseline to visit 4.

Visit	Statistic	t Value	DF	Prob
Baseline to Visit 3	Paired t test	-15.84	14	<.0001
Baseline to Visit 4	Paired t test	-25.66	14	<.0001

Recent research emphasizes the significance of monitoring postprandial blood sugar (PPBS) in the management of type II diabetes. According to Herath et al. (2017), PPBS monitoring is equally beneficial as FBS monitoring in optimizing glycemic management (Herath et al. 2017). In their study, Vani and Renuka (2020) found that there was a more pronounced link between PPBS and HbA1c when compared to FBS. This highlights the need of using PPBS to evaluate glycemic management (Vani and Renuka 2020). In a study conducted by Kumar et al. (2016), a meta-analysis revealed that including yoga as an additional treatment resulted in a substantial improvement in FBS, PPBS, and HbA1c levels among individuals with diabetes (Kumar et al. 2016). Ahmed (2019) found that diabetic patients had markedly elevated levels of FBS and PPBS compared to the control group. The findings indicate that monitoring PPBS is essential for efficient diabetes management. In addition, unconventional methods such as yoga can enhance the effectiveness of conventional therapy in improving glycemic control (Ahmed 2019). These studies highlight the significance of taking into account both FBS and PPBS in the holistic management of type II diabetes.

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Figure.3. PPBS mean score

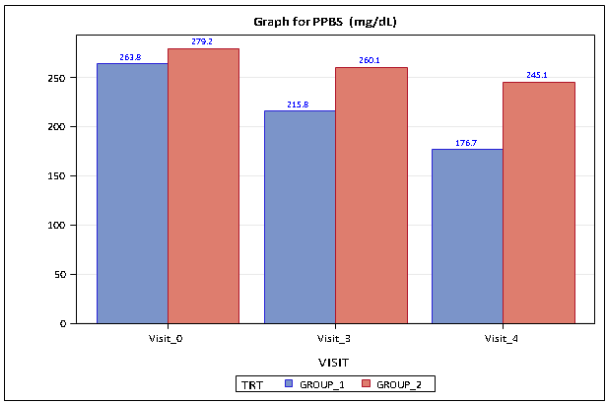

Figure 3 shows the mean PPBS score for active and placebo during trial visits. The graph shows that study product responders on Visit 3 and Visit 4 from Baseline differed between groups. At baseline, active and placebo individuals had mean values of 263.8 and 279.2. On Visit 3, active participants had a very substantial decrease in PPBS (215.8) compared to placebo (260.1). Active individuals had a 176.7 PPBS decrease on Visit 4 compared to 245.1 for placebo. In Table 11, participants on active had a minimum PPBS score of 210.0 and a maximum of 305.0. On week 12 (visit 3), PPBS scoring decreased from 210.0 to 190.0 and maximum score from 305.0 to 270.0. In week 24 (visit 4), the minimum PPBS score decreased from 210.0 to 145.0, while the maximum score decreased from 305.0 to 238.0. For placebo subjects, the minimum PPBS score was 254.0 and the maximum was 300.0.

Table. 11. Descriptive Stats - Improvement of PPBS from baseline to visit 3, baseline to visit 4 and within active and placebo.

Parameter/Statistics	Visit	Active	Placebo
PPBS (mg/dL)			
n	Screening	15	15
Mean (SD)	Screening	263.8(27.84)	279.2(14.47)
Median	Screening	260.0	286.0
Min, Max	Screening	210.0,305.0	254.0,300.0
n	Visit 3	15	15
Mean (SD)	Visit 3	215.8(25.39)	260.1(14.50)
Median	Visit 3	210.0	260.0
Min, Max	Visit 3	190.0,270.0	240.0,290.0
n	Visit 4	15	15
Mean (SD)	Visit 4	176.7(26.35)	245.1(16.52)
Median	Visit 4	178.0	245.0
Min, Max	Visit 4	145.0,238.0	221.0,276.0

Week 12 (visit 3) PPBS scoring decreased from 254.0 to 240.0 and maximum to 290.0 from 300.0. Visit 4 of week 24 saw PPBS scores decrease from 254.0 to 221.0 and from 300.0 to 276.0. The p-value for active subjects compared to placebo on week 12 (visit 3) was very significant (p-value - <.0001). The p-value for active subjects compared to placebo on week 24 (visit 4) was very significant (p-value - <.0001).

Table. 12. p value Between Treatments (Active vs. Placebo) for improvement of PPBS - baseline to visit 3 and baseline to visit 4.

Visit	Statistic	t Value	DF	Prob
Baseline to Visit 3	Ancova	-5.84	28	<.0001
Baseline to Visit 4	Ancova	-9.98	28	<.0001

Table.13. The p value data indicates variation from baseline to visits 3 and 4 in active and placebo treatment groups.

Visit	Statistic	t Value	DF	Prob
Baseline to Visit 3	Paired t test	-10.98	14	<.0001
Baseline to Visit 4	Paired t test	-21.62	14	<.0001

The studies collectively emphasize the crucial significance of lipid abnormalities in type II diabetes. Vergès (2009) highlights that individuals with diabetes frequently have qualitative abnormalities in their LDL cholesterol, such as tiny dense particles and oxidized LDL, which contribute to the development of atherosclerosis (Vergès 2009). Patil et al. (2017) discovered that diabetes individuals had notably elevated levels of total cholesterol (TC) and triglycerides (TG), as well as reduced levels of HDL-C, in comparison to the control group (Patil et al. 2017). In their study, Song et al. (2016) showed that the TC/HDL-C ratio was more effective than other lipid markers in distinguishing between patients with diabetes and those without diabetes. They found that a cutoff point of 1.30 mmol/L was the most appropriate threshold (Song et al. 2016). In a study conducted by Sabahelkhier et al. (2016), it was shown that diabetic patients had elevated levels of total cholesterol (TC), triglycerides (TG), and low-density lipoprotein cholesterol (LDL-C), whereas their high-density lipoprotein cholesterol (HDL-C) levels were lower compared to non-diabetic individuals (Sabahelkhier et al. 2016). These findings highlight the significance of regular lipid profile testing in patients

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with type II diabetes for the early detection and treatment of dyslipidemia, which may decrease the likelihood of cardiovascular problems linked to the condition.

Figure. 4. Mean value of Total Cholesterol

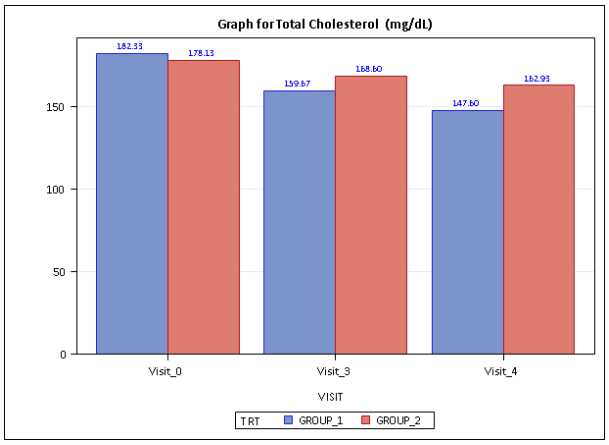
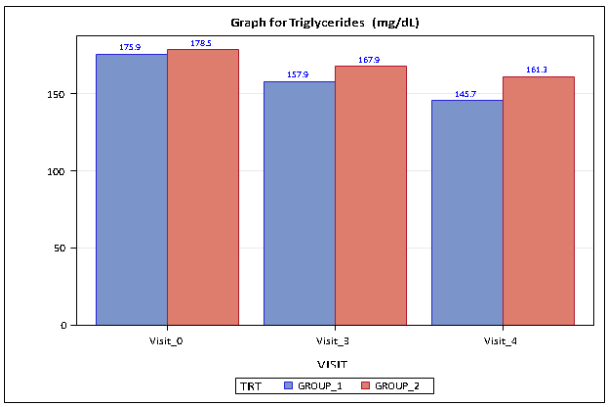


Figure 4 shows the mean Total Cholesterol scores for active and placebo participants during the study visits. The prevalence of study product responders varied between groups. On Visit 3 and 4, active subjects showed a significant decrease in Total Cholesterol (TC) compared to placebo. The minimum TC score for active subjects was 159, while for placebo subjects it was 149. The graph highlights the differences in TC scores between groups.

The study found that active participants showed significantly higher p-values at week 12 (visit 3) and week 24 (visit 4) compared to placebo participants (Table 15). The p-value data shows the degree of variance seen between the baseline visit and visits 3 and 4 within the treatment group, for both the active and placebo conditions (Table 16).

Figure.5. Mean value of Triglycerides



The figure 5 shows the mean Triglycerides scores for active and placebo participants during the study visits. The prevalence of study product responders varied between groups. On Visit 3 and 4, active subjects showed a significant decrease in Triglycerides, with a minimum score of 130 and a maximum score of 194. The minimum and maximum scores for placebo subjects decreased from 154 to 211. (Table 14). The p-value for week 12 (visit 3) was shown to be extremely significant (p-value = 0.0104) for patients who received the active treatment compared to those who received the placebo during this visit. The p-value for week 24 (visit 4) was extremely significant (p-value = 0.0006) for patients who received the active treatment compared to those who received the placebo during this visit (Table 15). The p-value data indicates the degree of change between the baseline visit and visits 3 and 4 in both the active and placebo groups within the treatment group (Table 16).

Table. 14. Descriptive Stats- Improvement of Lipid Profile from baseline to visit 3, baseline to visit 4 and within active and placebo.

Parameter/Statistics	Visit	Active	Placebo
Total Cholesterol (mg/dL)			
n	Screening	15	15
Mean (SD)	Screening	182.3(15.78)	178.1(15.63)
Median	Screening	185.0	177.0
Min, Max	Screening	159.0,212.0	149.0,205.0
n	Visit 3	15	15
Mean (SD)	Visit 3	159.7(13.66)	168.6(15.89)
Median	Visit 3	160.0	170.0
Min, Max	Visit 3	140.0,190.0	130.0,195.0
n	Visit 4	15	15
Mean (SD)	Visit 4	147.6(14.21)	162.9(15.45)
Median	Visit 4	145.0	165.0
Min, Max	Visit 4	130.0,175.0	125.0,185.0
Triglycerides (mg/dL)			
n	Screening	15	15
Mean (SD)	Screening	175.9(18.54)	178.5(19.99)
Median	Screening	181.0	172.0
Min, Max	Screening	130.0,194.0	154.0,211.0
n	Visit 3	15	15
Mean (SD)	Visit 3	157.9(17.12)	167.9(21.92)
Median	Visit 3	160.0	160.0
Min, Max	Visit 3	120.0,182.0	140.0,205.0
n	Visit 4	15	15
Mean (SD)	Visit 4	145.7(15.80)	161.3(19.55)
Median	Visit 4	145.0	152.0
Min, Max	Visit 4	115.0,168.0	135.0,196.0
LDL (mg/dL)			
n	Screening	15	15
Mean (SD)	Screening	95.1(7.69)	101.1(15.05)
Median	Screening	95.0	101.8
Min, Max	Screening	77.6,111.2	70.6,123.8
n	Visit 3	15	15
Mean (SD)	Visit 3	71.5(8.31)	91.7(15.86)

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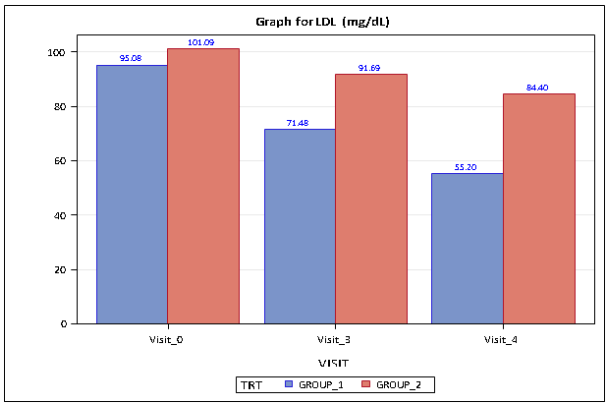
Median	Visit 3	69.6	94.4
Min, Max	Visit 3	58.0,91.6	50.4,115.0
n	Visit 4	15	15
Mean (SD)	Visit 4	55.2(11.11)	84.4(16.41)
Median	Visit 4	56.0	90.0
Min, Max	Visit 4	39.0,75.0	43.0,103.0
HDL (mg/dL)			
n	Screening	15	15
Mean (SD)	Screening	51.9(8.99)	41.3(2.82)
Median	Screening	56.0	41.0
Min, Max	Screening	40.0,62.0	36.0,47.0
n	Visit 3	15	15
Mean (SD)	Visit 3	56.6(8.41)	43.3(2.66)
Median	Visit 3	60.0	44.0
Min, Max	Visit 3	43.0,68.0	40.0,48.0
n	Visit 4	15	15
Mean (SD)	Visit 4	63.3(7.01)	46.3(4.32)
Median	Visit 4	65.0	45.0
Min, Max	Visit 4	50.0,70.0	40.0,56.0

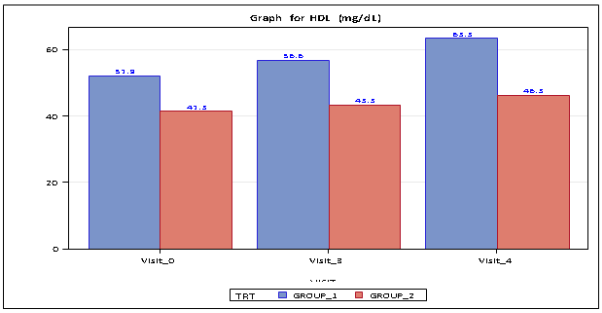
Figure. 6. Mean value of LDL



The figure 06 shows the mean LDL scores for active and placebo participants during the study visits. The mean values were 95.08 and 101.09 respectively. On Visit 3, active subjects showed a significant decrease in LDL, while on Visit 4, they showed a decrease. The minimum LDL score for active subjects was 77.6, while for placebo subjects it was 70.6. The mean scores decreased from 95.1 to 55.2, and from 101.1 to 84.4 (Table 14). The study found that active participants showed significantly higher p-values at week 12 (visit 3) and week 24 (visit 4) compared to placebo participants (Table 15). The p-value data indicates the degree of change between the baseline visit and visits 3 and 4 in both the active and placebo groups within the treatment group (Table 4).

Figure.7. Mean value of HDL

Fig: 07: Mean value of HDL



The figure 07 shows the mean HDL scores for active and placebo participants during study visits. The mean values were 51.9 and 41.3 respectively. Active subjects showed a significant increase in HDL on Visit 3 and 4, while active subjects had a minimum score of 40.0 and maximum score of 62.0. The minimum and maximum HDL scores for placebo subjects were 36.0 to 47.0 (Table 14).

The study found that active participants showed significantly higher p-values on week 12 (visit 3) and week 24 (visit 4) compared to placebo participants.

Table. 15. p value Between Treatments (Active vs. Placebo) for improvement of Lipid profile - baseline to visit 3 and baseline to visit 4.

Total Cholesterol				
Visit	**Statistic**	**t Value**	**DF**	**Prob**
Baseline to Visit 3	Ancova	-5.52	28	<.0001
Baseline to Visit 4	Ancova	-7.75	28	<.0001
Triglycerides				
Visit	**Statistic**	**t Value**	**DF**	**Prob**
Baseline to Visit 3	Ancova	-2.75	28	0.0104
Baseline to Visit 4	Ancova	-3.88	28	0.0006
LDL				
Visit	**Statistic**	**t Value**	**DF**	**Prob**
Baseline to Visit 3	Ancova	-5.92	28	<.0001
Baseline to Visit 4	Ancova	-8.27	28	<.0001
HDL				
Visit	**Statistic**	**t Value**	**DF**	**Prob**
Baseline to Visit 3	Ancova	3.63	28	0.0011
Baseline to Visit 4	Ancova	4.31	28	0.0002

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The p-value data indicates the degree of variance between the baseline visit and visits 3 and 4 within the treatment group, for both the active and placebo conditions.

Within the treatment both active and placebo showed improvement from baseline. Placebo subjects have shown improvement because the subjects on placebo were also on regular OHA, diet and exercise as the subjects on Active. But between active subjects and placebo subjects, active showed statistically high significance which was the efficacy end point of the study.

Table. 16. p value within Treatments (Active) for improvement of Lipid Profile - baseline to visit 3 and baseline to visit 4

Visit	Statistic	t Value	DF	Prob
Total Cholesterol				
Baseline to Visit 3	Paired t test	-11.24	14	<.0001
Baseline to Visit 4	Paired t test	-15.68	14	<.0001
Triglycerides				
Baseline to Visit 3	Paired t test	-9.40	14	<.0001
Baseline to Visit 4	Paired t test	-11.43	14	<.0001
LDL				
Baseline to Visit 3	Paired t test	-11.53	14	<.0001
Baseline to Visit 4	Paired t test	-15.73	14	<.0001
HDL				
Baseline to Visit 3	Paired t test	7.16	14	<.0001
Baseline to Visit 4	Paired t test	9.13	14	<.0001

Physical examination, vitals and Laboratory analysis (CBC, SGOT, SGPT, Serum creatinine and Uric acid) all were within normal limit from the start of the study till the end. Potassium and CRP showed reduction from screening to visit 4. Which is very significant with respect to safety of the product. From this we can conclude that study product (Amrith Noni D Plus) is not only effective but also very much safe to be taken as a treatment for Type II Diabetic Mellitus. No Adverse Events were reported by any of the subjects.

This suggests that the blood glucose levels of the intervention group and the control group differed noticeably. In conclusion, Amrith Noni D Plus can lower blood glucose levels since it contains Noni and other potent anti-diabetic herbs. A hypoglycaemic reaction is the result. To lower blood sugar levels and improve overall health, diabetic patients may be advised by medical practitioners to consume Amrith Noni D Plus.

Ethical Conduct of the Study

The Supplements and Cosmetics Act, 1940 of India, Supplements and Cosmetics Rules, 1945 of India, Ethical Guidelines for Biomedical Research on Human Participants, 2006 of the Indian Council of Medical Research (ICMR) in India, the principles stated in the Helsinki Declaration (Edinburgh, 2000), and the ICH-harmonized tripartite guideline regarding Good Clinical Practice (GCP) were all followed in the conduct of this study. The EC complies with CDSCO regulations, as does the ethics committee that is registered with CDSCO. EC ensures that the experiment it has approved complies with CDSCO and GCP guidelines. The study protocol and related documents were reviewed by the below listed Institutional Ethics Committee prior to study initiation. This IEC functions independent of Valyou Products Private Limited (Sponsor) or Syncretic Clinical Research Services Pvt. Ltd. (CRO) and the operations were in compliance with Part 56 of Title 21 of the Code of Federal Regulations (CFR) and International Conference on Harmonization (ICH) guidelines. The ethics committees gave a favourable opinion on the trial; Appendix 15.1 contains the IECs information and approval letter. This Ethics Committee was registered under CDSCO as per the Gazette Notification Number F.28-10/45-H (1), dated 21 DEC 1945 and last amended vide notification number G.S.R. 76(E) dated 21DEC2017. The EC registration number is ECR/809/Inst/KA/2017.

4. Discussion

As a result of this study, there were no adverse effects noticed, and the vital signs improved from the day of screening to the visit that took place 24 weeks later. Considering advantage of all of this, we are able to derive the conclusion that the drug under investigation, Amrith Noni D Plus, is not only effective but also extremely safe for use as a treatment for type 2 diabetes mellitus.

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