Clinical Trial Details

CTRI Number	CTRI/2025/10/095664 [Registered on: 06/10/2025] - **Trial Registered Prospectively**
Last Modified On	12/06/2026
Post Graduate Thesis	No
Type of Trial	Interventional
Type of Study	Nutraceutical
Study Design	Randomized, Parallel Group Trial
Public Title of Study	Study to Evaluate the Efficacy and Safety of Antox-D Liquid in People with Type 2 Diabetes
Scientific Title of Study	A randomized, double-blind, parallel-arm clinical trial to assess the efficacy and safety of a Health supplement (Antox-D liquid) in participants with type 2 diabetes mellitus.

Secondary IDs if Any

Secondary ID	Identifier
MHC/CT/25-26/007 Version: 2.00; dated 31st July 2025	Protocol Number

Details of Principal Investigator

Details of Principal Investigator	
Name	Dr Anuja Mukesh Phalak
Designation	Principal Investigator
Affiliation	Omkar Multispecialty Hospital
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Details Contact Person (Scientific Query)

Details Contact Person (Scientific Query)	
Name	Pradeep Patil
Designation	Partner
Affiliation	Improva Herbal Products
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Details Contact Person (Public Query)

Details Contact Person (Public Query)

Name	Sadik Shaikh
Designation	Director
Affiliation	Nutrifeel Health Products Pvt. Ltd
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Source of Monetary or Material Support

Source
Improva Herbal Products Gat No. 112, Murhe Vasti, At Post Kuruli Tal Khed Dist Pune 410501, Pune, Maharashtra

Primary Sponsor

Primary Sponsor Details	
Name	Nutrifeel Health Products Pvt. Ltd
Address	At post: Kundalwadi, Tal: Walva, Sangli, Maharashtra, 415411.
Type of Sponsor	Other [Nutraceutical]

Details of Secondary Sponsor

Name	Address
NIL	-

Countries of Recruitment

List of Countries
India

Sites of Study

Principal Investigator	Site Name	Address	Contact
Dr Dnyaneshwar Manwatkar	Care multispeciality hospital	Kolte arcade, Nagar Rd, Wagholi, Pune, Maharashtra 412207 Pune, MAHARASHTRA	7769068455
Dr Anuja Mukesh Phalak	Omkar Multispeciality Hospital	Survey No 94, Plot No 81, opposite to Yashada Windosong, Ravet, Pune, Pimpri-Chinchwad, Maharashtra 412101 Pune, MAHARASHTRA	9960789068 anujarnp@gmail.com

Details of Ethics Committee

Name	Approval Status
Care Multispeciality Hospital Institutional Ethics Committee	Approved
Institutional Ethics Committee Sangvi Multispeciality Hospital	Approved

Regulatory Clearance Status from DCGI

Status
Not Applicable

Health Condition / Problems Studied

Health Type	Condition
Patients	Type 2 diabetes mellitus without complications

Intervention / Comparator Agent

Type	Name	Details

Intervention	Group A: Health supplement + Oral hypoglycemic agents (OHA).	Take 10 ml twice daily, one hour before lunch and dinner, with water for 90 days
Comparator Agent	Group B: Placebo intervention + OHA	Take 10 ml twice daily, one hour before lunch and dinner, with water for 90 days

Inclusion Criteria

Inclusion Criteria	
Age From	30.00 Year(s)
Age To	65.00 Year(s)
Gender	Both
Details	1. Male and female participants aged between 30 and 65 years (both inclusive) 2. Participants receiving oral hypoglycemic agents, biguanides, and sulfonylureas (Only combination) 3. Glycated hemoglobin (HbA1c) greater than 7% and less than 9 % (both inclusive) 4. Participants willing to comply with the study procedure and sign the written informed consent 5. Participants with a BMI of less than 30 kg/m2

Exclusion Criteria

Exclusion Criteria	
Details	1. Participant with Type 1 diabetes mellitus; 2. Participant taking antidiabetic drugs except for those specified in the inclusion criteria, including Insulin treatment; 3. Participants with concurrent serious hepatic dysfunction (defined as AST and/or ALT more than 3 times the upper normal limit) or renal dysfunction (defined as S. creatinine greater than 1.4 mg/dl), uncontrolled pulmonary dysfunction (asthmatic and COPD patients), or other concurrent severe disease 4. Participants suffering from major systemic illness necessitating long-term drug treatment including but not limited to hematologic conditions (e.g., hemolytic anemias, sickle cell anemia), acute myocardial infarction, unstable angina, uncontrolled hypertension, congestive heart failure (class III or class IV NYHA), or cerebrovascular accident, psychiatric or neurological disorder, autoimmune condition, received chronic (more than 14 days) therapy with systemic glucocorticoids (excluding topical, intraocular, intranasal, intra-articular, or inhaled preparations) within six months prior to enrollment 5. Participants who are smokers/alcoholics and/or known drug abusers 6. Participants with evidence or history of malignancy 7. Participant enrolled in any other clinical trial requiring drug therapy 8. Pregnant or lactating women or women of fertile age not using effective contraception 9. Any condition that could, in the opinion of the investigator, preclude the participants ability to complete the study or that may confound study outcomes

Method of Generating Random Sequence

Computer generated randomization

Method of Concealment

Case Record Numbers

Blinding/Masking

Participant and Investigator Blinded

Primary Outcome

Outcome	Timepoints
1. Assessment of changes in HbA1c levels and Fasting and post-meal plasma glucose will be done 2. Assessment of changes in insulin resistance (HOMA-IR) will be assessed	1.at screening and day 90 and baseline, day 30, day 60, and day 90. 2.at the baseline and day 90.

Secondary Outcome

Outcome	Timepoints

1. Assessment of change in lipid profile will be done 2. Assessment of changes in metabolic syndrome severity Z score (MetS Z score) will be assessed 3. Assessment of change in anthropometric parameters will be performed 4. Assessment of changes in serum C-reactive protein (CRP) levels will be assessed 5. Assessment of change in fatigue severity scale score (FSS) will be done 6. Assessment of change in diabetes related quality of life by DQOL will be done	1.at baseline and day 90. 2.at baseline and day 90. 3.at screening, day 30, day 60, and day 90. 4. at the baseline and day 90 5. at baseline, day 30, day 60, and day 90. 6. at the baseline and day 90.

Target Sample Size	Total Sample Size: **100** Sample Size from India: **100** Final Enrollment (Total): **104** Final Enrollment (India): **104**
Phase of Trial	Phase 2
Date of First Enrollment (India)	13/10/2025
Date of First Enrollment (Global)	No Date Specified
Date of Study Completion (India)	16/03/2026
Date of Study Completion (Global)	No Date Specified
Estimated Duration of Trial	Years: 0, Months: 6, Days: 0
Recruitment Status (Global)	Not Yet Recruiting
Recruitment Status (India)	Completed
Publication Details	N/A
Brief Summary	This randomized, double-blind, placebo-controlled clinical study was conducted to evaluate the efficacy and safety of Antox-D supplementation in participants with type 2 diabetes mellitus and associated metabolic abnormalities over a 90-day treatment period. Eligible participants were randomized to receive either Antox-D or placebo along with standard of care, and assessments were performed at predefined study visits including screening, Day 60, and Day 90. Primary and secondary efficacy parameters included glycemic control, insulin resistance markers, metabolic syndrome severity, lipid profile, anthropometric measurements, fatigue severity, and diabetes-related quality of life. Antox-D supplementation demonstrated significant improvement in glycemic parameters compared with placebo. HbA1c levels decreased significantly from 7.48 ± 0.32% at screening to 6.85 ± 0.36% at Day 90 in the Antox-D group, corresponding to an 8.34% reduction compared with a 2.72% reduction in the placebo group ($p = 0.0002$). Fasting plasma glucose showed statistically significant between-group differences at Day 60 ($p = 0.028$) and Day 90 ($p = 0.002$), while postprandial plasma glucose levels demonstrated greater numerical reduction in the Antox-D group compared with placebo. Significant improvements were also observed in insulin resistance parameters, including reductions in fasting insulin levels and HOMA-IR, with the latter showing a 16.49% decrease in the Antox-D group compared with a 2.77% increase in the placebo group ($p = 0.0004$).

Participants receiving Antox-D also demonstrated significant improvement in metabolic and clinical outcomes. Metabolic syndrome severity, assessed using MetS Z score, showed a 35.47% reduction in the Antox-D group compared with a 2.43% increase in the placebo group ($p = 0.027$). Favorable effects on lipid parameters were observed, including a statistically significant reduction in LDL cholesterol ($p = 0.0006$), along with numerical improvements in total cholesterol, triglycerides, and VLDL cholesterol. Significant reductions in body weight and BMI were also reported in the Antox-D group. Additionally, participants experienced improvement in fatigue severity and diabetes-related quality of life across multiple domains, including treatment satisfaction, diabetes management, exercise, routine diabetes check-ups, and disease-related knowledge.

Antox-D was found to be safe and well tolerated throughout the study duration. No serious adverse events, clinically significant safety concerns, or investigational product-related discontinuations were reported. Serum CRP levels did not show statistically significant changes between groups during the study period. Overall tolerability remained within the “excellent tolerability” category in both treatment groups. Based on the study findings, Antox-D demonstrated clinically meaningful benefits in glycemic control, insulin resistance, metabolic health, and quality of life with a favorable safety and tolerability profile over 90 days of supplementation.