HUNTERTrial

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Protocol at a Glance

HSE-T2D-001: A Phase Ib/IIa Study of Hunteria umbellata Seed Extract for Early Type 2 Diabetes Remission

Quick Facts

Protocol ID:	HSE-T2D-001	**Phase:**	Ib/IIa
Sample Size:	60 participants	**Duration:**	12 weeks + 2-week follow-up
Study Type:	Randomized, Double-Blind, Placebo-Controlled		

Study Rationale

Early type 2 diabetes (diagnosed within 12-24 months) represents a critical window for potential remission. Intensive lifestyle intervention can achieve up to 77% remission rates, yet no low-cost, orally available adjuvants exist to enhance these outcomes. *Hunteria umbellata* seed extract (HSE-01) is a novel alpha-glucosidase inhibitor with preclinical evidence showing **2.67× faster glucose reduction** compared to metformin in diabetic rat models.

Primary Objectives

- **Safety & Tolerability:** Assess adverse events, laboratory safety parameters, and treatment discontinuations
- **Preliminary Efficacy:** Evaluate change in fasting plasma glucose from baseline to Week 12
- **Dose-Ranging:** Compare low-dose vs. high-dose HSE-01 to inform Phase IIb dosing

Study Design

Arm	Intervention	N	Duration
Arm 1	HSE-01 Low Dose + Intensive Lifestyle	20	12 weeks
Arm 2	HSE-01 High Dose + Intensive Lifestyle	20	12 weeks

Arm 3	Placebo + Intensive Lifestyle	20	12 weeks

Lifestyle Intervention: Mediterranean diet (1,500-1,800 kcal/day) + structured exercise (150 min/week)

Eligibility Criteria

Key Inclusion Criteria:

- Adults aged 30-65 years
- Type 2 diabetes diagnosed ≤24 months ago
- HbA1c 6.5-9.0% at screening
- BMI 25-35 kg/m²
- Willing to discontinue antidiabetic medications (if any) after 2-week washout
- Willing to adhere to Mediterranean diet and exercise program

Key Exclusion Criteria:

- Type 1 diabetes or secondary diabetes
- Insulin therapy within past 3 months
- Severe hepatic impairment (ALT/AST >3× ULN)
- Chronic kidney disease (eGFR <45 mL/min/1.73m²)
- History of diabetic ketoacidosis
- Pregnancy or breastfeeding

Study Endpoints

Category	Endpoints
Primary Safety	• Incidence of adverse events (AEs) and serious AEs • Treatment discontinuations due to AEs • Hypoglycemia events (Level 1, 2, 3)
Primary Efficacy	• Change in fasting plasma glucose from baseline to Week 12
Secondary Efficacy	• Change in HbA1c • Postprandial glucose (2-hour meal tolerance test) • Insulin sensitivity (HOMA-IR)

	• Beta-cell function (fasting C-peptide) • Lipid profile (TC, LDL, HDL, TG) • Body composition (weight, BMI, waist circumference) • Blood pressure • Remission rate (HbA1c <6.5% or <5.7%)

Study Timeline

Phase	Timeline	Activities
Screening	Week -2 to 0	Eligibility assessment, informed consent, baseline labs
Baseline & Randomization	Week 0	Comprehensive baseline assessment, lifestyle counseling, drug dispensing
Treatment Period	Weeks 1-12	Clinic visits at Weeks 4, 8, 12; home glucose monitoring; adherence check-ins
Safety Follow-Up	Week 14	Post-treatment assessment (phone call); final adverse event review

Safety Monitoring

- **Data Safety Monitoring Board (DSMB):** Independent oversight; quarterly reviews
- **Hypoglycemia Protocol:** Pre-defined management algorithm for glucose <70 mg/dL
- **Laboratory Safety:** CBC, CMP, LFTs at baseline and Weeks 4, 8, 12
- **Stopping Rules:** Pre-specified criteria for early termination or dose modification

Regulatory & Ethical Framework

- **FDA Guidance:** Aligned with FDA Botanical Drug Development Guidance (2016)
- **ICH-GCP:** Conducted per ICH E6(R2) Good Clinical Practice guidelines
- **IRB Approval:** Required before enrollment; annual continuing review
- **Informed Consent:** Written informed consent obtained from all participants
- **ClinicalTrials.gov:** Prospectively registered before first participant enrolled

Statistical Analysis

Sample Size Justification: N=60 (20 per arm) provides 80% power to detect a 20 mg/dL difference in fasting glucose (SD=25 mg/dL, α=0.05, two-sided).

Primary Analysis: ANCOVA with baseline glucose as covariate. Intent-to-treat (ITT) population for efficacy; safety population includes all participants receiving ≥1 dose.

Interim Analysis: DSMB will conduct one interim safety analysis after 30 participants complete 4 weeks.

Contact Information

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