# Lembas Edge – A Peptide Developed to Support Glucose Control: First-in-Human Clinical Trial of Tolerability and Postprandial Glycemic Response

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Lembas
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## Background

Obesity is a main risk factor for prediabetes and type 2 diabetes; **87.5%** of people diagnosed with diabetes are overweight or obese.

Managing **postprandial glycemia and satiety** is a key strategy for weight management.

**Lembas Edge** is a peptide fragment of alpha-galactosidase, a digestive enzyme with FDA GRAS status (GRN 1120). In diet-induced obese rats (28 days) it **reduced body weight and food intake**, with no toxicity.

## Objectives

**Part 1:** tolerability of Lembas Edge in healthy adults.

**Part 2:** efficacy of Lembas Edge on postprandial glycemic control in prediabetic overweight and obese adults.

## Methods

### Part 1 · Tolerability

- Single-arm, open-label; **n = 5** healthy adults ≥18 y
- Lembas Edge 3 × 45 mg capsules daily (**135 mg/day**) for **14 days**
- Safety: AEs, vital signs, clinical chemistry, CBC; fasting glucose, insulin, HOMA-IR

### PART 2 · RANDOMIZED 4-WAY CROSSOVER DESIGN

Triple-blind, placebo-controlled · **n = 30** prediabetic adults · **each participant is their own control**

**Period 1** Visit 2 · Day 1 → ≥6 d washout → **Period 2** Visit 3 · Day 8 → ≥6 d washout → **Period 3** Visit 4 · Day 15 → ≥6 d washout → **Period 4** Visit 5 · Day 22

Every participant receives **all four treatments**, one per period, in randomized order

| Treatment | Capsules (identical) | Dose |
|---|---|---|
| **High** | 3 Lembas Edge | 135 mg |
| **Medium** | 2 Lembas Edge + 1 placebo | 90 mg |
| **Low** | 1 Lembas Edge + 2 placebo | 45 mg |
| **Placebo** | 3 placebo | 0 mg |

#### Outcomes

- **Primary:** glucose iAUC$_{0–120\ min}$; glucose peak & nadir
- **Secondary:** insulin & satiety iAUC; ad libitum energy intake
- **Analysis:** linear mixed models (visit, sequence, product)

## Part 2 Test Day

| | |
|---|---|
| **−120 min** | Capsules taken fasted |
| **0 min** | Standard breakfast: bagel, butter, orange juice (~80 g carbohydrate) |
| **0–240** | Glucose, insulin & hunger/fullness ratings |
| **240 min** | Ad libitum meal; energy intake |

## Results

### Part 1 · Tolerability

**5**
participants

**14**
days of Lembas Edge

**0**
signs of toxicity or inconvenience

**Part 2:** ongoing

## Conclusions

Lembas Edge was tolerated with no signs of toxicity or inconvenience, supporting progression to Part 2, which will define its dose effects on postprandial glycemia and satiety.