Mini Clinical Research Project Protocol

Study Title: Evaluation of Device Safety & Efficacy in Type 2 Diabetes Patients

Objective: To evaluate the safety and efficacy of a novel medical device in managing glucose levels.

Study Design: Randomized, open-label, parallel-group pilot study.

Sample Size: 30 patients (15 per group)

Duration: 12 weeks

Primary Endpoint: Change in fasting blood glucose levels from baseline.

Secondary Endpoints: HbA1c, adverse events, patient compliance.

Inclusion Criteria: Adults (18–65 yrs) with diagnosed T2DM.
Exclusion Criteria: Severe comorbidities, pregnancy, non-consent.

Ethics: Study will follow ICH-GCP guidelines.