

Magnetic Compression Anastomosis Procedure for Partial Jejunioileal Anastomosis: Assessing the Viability of an Innovative Metabolic Approach

NCT07495787

Status	RECRUITING
Phase	Not Applicable
Sponsor	iIDEAS Group Holdings Limited
Enrollment	5 participants

Key Eligibility Criteria

Inclusion (8)

- Subjects will be included in the study if they meet the following criteria:
- Participant is willing and able to give informed consent for participation in the study.
- Male or Female, aged e 25 years to d 65 years.
- BMI greater than or equal to 25 and less than 50
- Clinical diagnosis of T2DM by plasma glucose criteria, either the fasting plasma glucose (FPG) value or the 2-h plasma glucose (2-h PG) value during a 75-g oral glucose tolerance test (OGTT), or A1C criteria
- ... and 3 more (see full listing online)

Exclusion (30)

- \. Pregnancy or breastfeeding mothers, or individuals planning to become pregnant in next 9-12 months
- 2. Vulnerable individuals (mentally disabled, physically disabled, prisoner, etc.)
- 3. Current enrolment in another research study or previous participation within 30 days of enrolment
- 4. Current history of injected Glucagon Like Peptide 1 (GLP1)
- 5. American Society of Anesthesiologists (ASA) physical classification level of 4 or greater
- 6. Hypoglycemia unawareness or a history of severe hypoglycemia (more than 1 severe hypoglycemic event, as defined by need for third-party-assistance, in the last year)
- 7. Evidence of type 1 diabetes or of pancreatic exhaustion, as indicated by a C peptide fasting level less than 1 or, for type 1 diabetes, based on measurable levels of serum anti-GAD-65 autoantibodies or, at investigator's discretion, based on measurable levels of other T1D-associated autoantibodies
- 8. History of highly unusual or challenging gastrointestinal tract anatomy ascertained through earlier endoscopic examination or other diagnostic imaging
- 9. History of (or known to be at prohibitive risk for) any of the following diseases of the small bowel or closely related conditions: Crohn's disease or other inflammatory bowel disease, celiac disease, resection for cancer, or intra-abdominal adhesive disease including intussusception, perforated appendix and Meckel's diverticulum
- 10. History of small bowel surgery such as small bowel resection
- 11. Active H. pylori infection (prospective participants with active H. pylori may continue with the screening process if they are treated via medication and re-testing verifies the condition has resolved.)
- 12. History of chronic or acute pancreatitis
- 13. Known active hepatitis or active liver disease
- 14. Symptomatic gallstones or kidney stones or acute cholecystitis
- Subjects will be deemed ineligible to participate if they fulfill any of the following criteria:
- Pregnancy or breastfeeding mothers, or individuals planning to become pregnant in next 9-12 months
- Vulnerable individuals (mentally disabled, physically disabled, prisoner, etc.)
- Current enrolment in another research study or previous participation within 30 days of enrolment
- ... and 25 more (see full listing online)

Locations (1 total)

AB Plus Speciality Hospital, Ahmedabad, Gujarat, India

<https://clinicaltrials.gov/study/NCT07495787>

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