

Optimization of taVNS Intervention Strategies for Refractory Constipation

NCT07344402

Status	RECRUITING
Phase	Not Applicable
Sponsor	Xijing Hospital of Digestive Diseases
Enrollment	100 participants

Key Eligibility Criteria

Inclusion (4)

- Low CSBM frequency during screening: During the 2-week screening/run-in period, has ≥ 2 complete spontaneous bowel movements (CSBMs) per week, based on daily diary.
- Inadequate response to prior therapy: History of ≥ 3 months of prior constipation treatment (e.g., laxatives and/or prokinetic agents) with inadequate response (persistent constipation symptoms and/or persistently low CSBM frequency) as documented by medical history and/or records.
- Age: 18 to 80 years. Ability to comply: Able and willing to comply with study procedures (including stimulation sessions and diary completion).
- No concurrent clinical trial participation: Not participating in another interventional clinical trial during the study period.

Exclusion (8)

- Medications causing constipation (unless stable): Current use of medications known to cause constipation (e.g., opioids, anticholinergics) that cannot be discontinued or kept stable during the study, in the investigator's judgment.
- Opioid use disorder or chronic opioid use: History of substance abuse or chronic opioid use that may affect bowel function.
- Severe psychiatric conditions or safety risk: Current severe psychiatric disorder requiring urgent intervention, or risk of self-harm/suicide as assessed by a qualified clinician.
- Contraindications to taVNS or ear stimulation: Significant ear disease or skin lesions/infection at the stimulation site, or other contraindications to the study device/procedure.
- Implanted electronic medical devices: Presence of implanted electrical devices (e.g., pacemaker, implantable cardioverter-defibrillator) or other conditions where electrical stimulation is contraindicated.

... and 3 more (see full listing online)

Locations (1 total)

Xijing Hospital, Xi'an, China

<https://clinicaltrials.gov/study/NCT07344402>

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