The effect of non-invasive transauricular vagus nerve stimulation on upper gastrointestinal motility in healthy individuals

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To study the impact of tVNS on gut motor function, in particular with regards to its potential to induce phase III contractions in the upper GI tract, in healthy subjects.

Ethical review	Approved WMO
Status	Pending
Health condition type	Gastrointestinal signs and symptoms
Study type	Interventional

Summary

ID

NL-OMON56970

Source
ToetsingOnline

Brief title
tVNS and upper GI motility

Condition

- Gastrointestinal signs and symptoms

Synonym
Gastric Motility

Research involving
Human

Sponsors and support

Primary sponsor: MDL
Source(s) of monetary or material Support: ERC grant

Intervention

Keyword: Healthy volunteers, MMC, tVNS, Upper GI Motility

Outcome measures

Primary outcome

Gut motor function measured with: phase III contractions

Secondary outcome

- Other gut motor parameters such as: migrating motor complex, duodenal phase

III contractions, the amplitude of antral contractions, motility index

- Plasma motilin and pancreatic polypeptide level

- Autonomic parameters such as heart rate variability

Study description

Background summary

Although motor function in the GI tract is intrinsically regulated by pacemaker cells of the enteric nervous system, there is a strong extrinsic influence via the efferent vagus. Motor responses in the upper GI tract, which is innervated by the vagus nerve, are characterized by stereotypical motility patterns called the migrating motor complex (MMC). Gastrointestinal rumbling, which is mainly noticed during fasting, is associated with the MMC. The MMC is an aborally propagating contractility complex during the fasting state, characterized by three different phases: phase I is a period of motor quiescence, phase II displays progressively increasing motor activity and phase III has the highest contractile activity and can start in either the stomach or small intestine.
The MMC moves from the stomach to the terminal ileum over a period of 1.5-2.0* hours and is interrupted by nutrient intake, after which the motor response switches to a less coordinated *fed pattern,* which usually lasts at least 2 hours after meal ingestion before the MMC returns. The vagus nerve plays an important role in the initiation of MMC that originate from the stomach, as vagotomy was shown to block MMCs. In addition, acute stress has been shown to inhibit MMCs.
Whether a disturbance in upper GI tract motility has a role in the development of abdominal symptoms remains a subject of debate. In this study, we aim to investigate whether tVNS is able to induce migrating motor complexes as a

result of stimulation of the vago-vagal intestinal reflex loop in healthy subjects.

Study objective

To study the impact of tVNS on gut motor function, in particular with regards to its potential to induce phase III contractions in the upper GI tract, in healthy subjects.

Study design

This is an intervention study with 12 healthy volunteers, aged 18-55 years old.

Intervention

During the eight-hour measurement period, one block of four hours will consist of tVNS, and one block of 4 hours will consist of sham-tVNS.

Study burden and risks

Participants will not benefit from participating in this study.
Insertion of the antroduodenal manometry catheter can be uncomfortable, but in most patients this feeling disappears after a few minutes. After the manometry patients can have a slight irritation of the nose or throat. The radiation exposure associated with fluoroscopy during the positioning of the catheter is minimal, with a total radiation exposure of approximately 0.05-1 mSv.
The collection of blood samples can bring along some slight risks, i.e. hematoma, bleeding, pain and/or vasovagal reaction during or after vena punction. Subjects will be seated on an examination bed, to prevent side effects to occur.
Participation in this study will cost some time. Subjects have to visit the hospital twice. The screening will take around 30-45 minutes. And the second visit will take around 9-10 hours.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

- Healthy participants (defined as those without a pre-existing medical comorbidity).
- Age between 18 and 55 years.
- Ability to understand and speak the Dutch language.

Exclusion criteria

- Pregnancy or lactation.
- Use of any substances (such as medication or recreational drugs) influencing gastrointestinal motility
- Not meeting the inclusion criteria above.
- Students and employees of Maastricht University are not precluded from participation, unless they have a direct personal, professional of hierarchical position with regards to any of the study team members or their department.

Study design

Design

Study phase: 2

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-12-2024
Enrollment:	12
Type:	Anticipated

Medical products/devices used

Generic name:	Transcutaneous Vagal Nerve Stimulation
Registration:	No

Ethics review

Approved WMO

Date:	26-08-2024
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL86446.068.24