# BURP trial

No registrations found.

| | |
|---|---|
| **Ethical review** | Not applicable |
| **Status** | Recruiting |
| **Health condition type** | - |
| **Study type** | Interventional |

## Summary

### ID

NL-OMON23976

**Source**
NTR

**Brief title**
BURP

**Health condition**

Inability to belch

### Sponsors and support

**Primary sponsor:** None
**Source(s) of monetary or material Support:** None

### Intervention

### Outcome measures

#### Primary outcome

the ability of UES relaxation in response to esophageal distention caused by ingested air as assessed with stationary high-resolution impedance manometry

#### Secondary outcome

- To evaluate the number and type of belches, their association with reported symptoms and underlying mechanism as assessed with ambulatory 24-h impedance pH-monitoring.

- To identify the number of transient lower esophageal relaxations (TLESRs)

- To identify secondary peristalsis in reaction to ingested air

- To assess esophageal motility, UES, and LES morphology (resting pressure, relaxation pressure, presence of hiatal hernia

- To evaluate quality of life and symptoms of patients before and after Botox treatment

- What is the role of aerofagia in patient with inability to belch?

# Study description

### Background summary

Inability to belch is a phenomenon of unknown aetiology. Patients may present with lifelong symptoms of chest pain and/or abdominal bloating. As the phenomenon is quite rare and barely described in literature, there are no current guidelines or supporting evidence for a standardized diagnostic or therapeutic approach in these patients. A recent study treated patients unable to belch with botulin toxin (botox) injection into the cricopharyngeus muscle. All patients were able to belch and reported symptom improvement after treatment, which might indicate a role of upper esophageal sphincter (UES) dysfunction. However, belching and underlying mechanisms have never been objectively investigated in a series of consecutive patients unable to belch. The aim of this study is to reveal the underlying physiological mechanisms associated with symptoms of inability to belch and to study the effect of UES botox injections on UES physiology.

### Study objective

We hypothesize that patients with symptoms of inability to belch have ineffective UES relaxation in response to esophageal distention caused by air.

### Study design

Baseline and <6 weeks >3 months post botox injections

### Intervention

High-resolution impedance manomotry monitoring before the scheduled botox treatment

# Contacts

**Public**
Amsterdam UMC
Renske Oude Nijhuis

+31205667805
**Scientific**
Amsterdam UMC
Renske Oude Nijhuis

+31205667805

# Eligibility criteria

## Inclusion criteria

- Written informed consent;
- Age above 18 years;
- Complains of inability to belch, for at least 3 months.

## Exclusion criteria

- Previous treatment for inability to belch
- History of pharyngeal or esophagal surgery or malignancies
- Use of medication affecting esophageal motility

# Study design

## Design

| | |
|---|---|
| Study type: | Interventional |
| Intervention model: | Other |
| Allocation: | Non controlled trial |
| Masking: | Open (masking not used) |
| Control: | N/A , unknown |

### Recruitment

NL

| | |
|---|---|
| Recruitment status: | Recruiting |
| Start date (anticipated): | 20-08-2019 |
| Enrollment: | 10 |
| Type: | Anticipated |

### IPD sharing statement

**Plan to share IPD:** Undecided

## Ethics review

Not applicable

| | |
|---|---|
| Application type: | Not applicable |

## 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 |
|---|---|
| NTR-new | NL8494 |
| Other | METC AMC : W19_307#19.365 |

## Study results