Effect of left and right lateral positioning on gastroesophagel reflux (GER) and underlying mechanisms in GER disease patients and healthy controls

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To investigate the influence of left and right lateral position on the onset of TLESRs and GER and the underlying mechanisms during and after a test meal in GERD patients compared to healthy controls.

Ethical review	Approved WMO
Status	Pending
Health condition type	Gastrointestinal motility and defaecation conditions
Study type	Observational invasive

Summary

ID

NL-OMON33184

Source
ToetsingOnline

Brief title
Posture and gastro-esophageal reflux in disease and health

Condition

- Gastrointestinal motility and defaecation conditions

Synonym
heartburn, Reflux

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum

Source(s) of monetary or material Support: Stichting Emma Kinderziekenhuis;club van 100

Intervention

Keyword: Gastric Emptying, Gastroesophageal reflux, Posture, Transient lower esophageal sphincter relaxations (TLESR)

Outcome measures

Primary outcome

1) Time to first TLESR 2) Number of TLESRs in the first 15 minutes 3) Total

number of TLESRs 4) Cumulative 13C excretion at first TLESR 5) Gastric volume

(number of voxels) at first TLESR.

Secondary outcome

1) Total number of acid/ weakly acidic/ weakly alkaline GER episodes 2) Total

number of liquid/mixed/gas GER 3) Total gastric volume (number of voxels) 4)

Total gastric emptying time

Study description

Background summary

The movement of gastric contents into the esophagus, gastro-esophageal reflux (GER) does not only occur in patients with GER disease (GERD) but is universal in healthy volunteers as well. When GER leads to symptoms or complications it is referred to as GERD. The underlying mechanism of GER is transient lower esophageal sphincter relaxation (TLESR) in GERD patients and in healthy volunteers. The number of GER episodes in healthy volunteers and GERD patients does not differ. However, in GERD patients, refluxate is more often acidic (pH<4) and liquid whereas it is more likely to be less acidic and gas-like in healthy volunteers. Not all mechanisms that trigger TLESRs have been elicited, however gastric distension and feedback mechanisms from the duodenum are known to induce TLESRs.
Recently, we investigated the influence of side positioning in infants. We demonstrated a reduction of number of TLESRs and liquid GER episodes in left lateral position (LLP) compared to right lateral position (RLP). We

subsequently studied the effect of lateral side positioning during meals and observed that the first TLESR in RLP is triggered much sooner and in some cases directly after infusing minute amounts of an infant formula. Gastric distension, nor duodenal feedback mechanisms can fully explain this early onset of triggering TLESRs. The volume needed to trigger TLESRs and GER have not been studied in adults and neither has the effect of posture on this.

Study objective

To investigate the influence of left and right lateral position on the onset of TLESRs and GER and the underlying mechanisms during and after a test meal in GERD patients compared to healthy controls.

Study design

A prospective, randomized, cross-over observational study. Patients and controls will not be informed about previous findings about the influence of posture on GER and TLESRs. Investigators will be blinded during the analysis.

Study burden and risks

Two nasogastric catheters will be inserted into the oesophagus and stomach. Subjects will receive a test meal via one catheter. A non invasive gastric emptying breathtest will be performed. Gastric volume scintigraphy using intravenously administered 99mTc-pertechnetate will be performed. Three questionnaires will be taken to assess gastrointestinal symptoms. This study will take approximately 2 hours and will be repeated once in the other lateral position. The above mentioned procedures might cause slight discomfort, but are not harmful. The radiation burden is within the acceptable limits for research with volunteers. Subject will not benefit directly from this study and will be compensated with ¤100,-.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

GERD
* Written informed consent.
* >18 yr of age.
* 2 of the following criteria:
o GERD proved by pH-monitoring with reflux index >5.8% (Richter et al 1992).
o Combined pH-MII monitoring with SAP>95%
o Reflux esophagitis * grade I as confirmed by endoscopy.
* GERD symptoms > 3 months and >2x per week.
Healthy controls
* Written informed consent.
* >18 yr of age.
* No GERD symptoms or

Exclusion criteria

Exclusion criteria
* Previous gastro-intestinal surgery (with the exception of appendectomy).
* Any condition that will make it unsafe the subject to participate.
* Congenital abnormalities affecting the gastro-intestinal tract.
* Mental retardation.
* Hiatus hernia.
* Gravida.
* Any condition that will make discontinuation of medication impossible, as determined by the treating physician.

Study design

Design

Study type:	Observational invasive
Intervention model:	Crossover
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-03-2009
Enrollment:	20
Type:	Anticipated

Ethics review

Approved WMO

Application type:	First submission
Review commission:	METC Amsterdam UMC

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	NL26741.018.09