Effect of graded running on gastroesophageal reflux

Published: 16-02-2015
Last updated: 21-04-2024

Primary Objective: To evaluate whether exercise leads to an increase total reflux time.
Secondary Objective(s): - To evaluate whether the increase in reflux correlates with: exercise intensity, failure of the LES to act as an effective barrier,...

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

Summary

ID

NL-OMON42100

Source
ToetsingOnline

Brief title
Exercise and reflux

Condition

- Gastrointestinal motility and defaecation conditions

Synonym
Pyrosis, reflux

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Europese Unie (Marie Curie)

Intervention

Keyword: Exercise, Gastroesophageal reflux, Reflux

Outcome measures

Primary outcome

Total reflux time (% of time with esophageal pH<4)

Secondary outcome

- Total number of reflux episodes (acid and non-acid)

- LES function

- Intra-abdominal pressure

- Esophageal motility

- Frequency of TLESRs

- Frequency of TLESRs with reflux

- Frequency of non-TLESR reflux events

- Reflux symptoms (heartburn, regurgitation)

Study description

Background summary

Gastroesophageal reflux disease (GERD) is caused by the reflux of gastric contents into the esophagus. GERD symptoms tend to be common among athletes, with epidemiological data indicating that upper gastrointestinal symptoms occur in up to 58% of surveyed athletes. Previous studies have shown that strenuous exercise can induce excessive reflux, both in patients with GERD and in asymptomatic healthy subjects, and that this mainly occurs during vigorous exercise, suggesting that strenuous physical activity can be a risk factor for GERD.

Currently, the mechanisms underlying excess reflux during exercise are unclear. Some studies suggest that reflux can influence athletic performance due to symptoms such as heartburn or regurgitation, but also due to an increased

airway resistance due to acid reflux, which could compromise maximal competitive performance.

Study objective

Primary Objective: To evaluate whether exercise leads to an increase total reflux time.

Secondary Objective(s):
- To evaluate whether the increase in reflux correlates with: exercise intensity, failure of the LES to act as an effective barrier, increased intra-abdominal pressure and reflux symptoms.
- To evaluate the effect of high-intensity exercise on esophageal motility, and more specifically the effect on peristaltic contractions.
- To evaluate the frequency of TLESRs during exercise.

Study design

A prospective observational design. Patients will run on a treadmill at predetermined rates and for different durations after placement of both an HRM catheter and a pH-impedance catheter.

Study burden and risks

There are no risks involved in the placement of the catheters for esophageal pH-impedance and pressure monitoring. The investigative procedure may induce some discomfort in the nose and throat. Participants will be compensated financially for participation in the study.

Contacts

Public
Academisch Medisch Centrum

Meibergdreef 9
Amsterdam-Zuidoost 1105AZ
NL
Scientific
Academisch Medisch Centrum

Meibergdreef 9
Amsterdam-Zuidoost 1105AZ
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Age 18 * 50 years
Frequent physical activity: at least 10 km of running a week

Exclusion criteria

History of peptic ulcer disease
Known Barrett*s oesophagus
History of GI cancer
GI tract surgery (except appendectomy)
Use of drugs that affect GI function
Other organic gastro-intestinal diseases or functional disorders such as irritable bowel syndrome or functional dyspepsia
Pregnancy

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	04-05-2015
Enrollment:	9
Type:	Actual

Ethics review

Approved WMO

Date:	16-02-2015
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	NL51220.018.14