Effect of capsaicin infusion on esophageal mucosal integrity * a role for TRPV1-mediated neuropeptides?

Published: 23-07-2015
Last updated: 14-04-2024

To investigate the effect of capsaicin infusion on mucosal integrity. We will evaluate mucosal impedance and the histology of the esophageal mucosa. In addition, we also aim to assess the involvement of the TRPV1 receptor by evaluating the possible...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Gastrointestinal conditions NEC
Study type	Interventional

Summary

ID

NL-OMON42198

Source
ToetsingOnline

Brief title
Capsaicin and mucosal integrity

Condition

- Gastrointestinal conditions NEC

Synonym
Gastroesophageal reflux disease, heartburn

Research involving
Human

Sponsors and support

Primary sponsor: Medisch Universitair Ziekenhuis Maastricht
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Capsaicin, GERD, Heartburn, TRPV1

Outcome measures

Primary outcome

Baseline impedance as measured in vivo after infusion with capsaicin and

control solution.

Secondary outcome

1. Intercellulair spaces using electron microscopy ruimte met elektronen

microscoop

2. Mucosal concentration of neuropeptides

3. Immunohistochemical expression of TRPV1

4. VAS scores for heartburn, retrosternal pain.

Study description

Background summary

Reflux is common, especially after large meals. In general, this can do no harm. However, if reflux occurs often and causes troublesome symptoms and or complications, it is called gastroesophageal reflux disease (GERD). Long exposure to gastric acid causes the mucosa of the esophagus to loose its integrity, which is thought to lead to the symptom of heartburn.

Several food products can also impair the esophageal mucosa integrity and thereby influence reflux symptoms. One of these products is capsaicin, the pungent ingredient of red peppers. Use of capsaicin often leads to worsening of complaints in patients with GERD and can cause symptoms in healthy volunteers, possibly due to its effect on the mucosal integrity.

Study objective

To investigate the effect of capsaicin infusion on mucosal integrity. We will evaluate mucosal impedance and the histology of the esophageal mucosa. In

addition, we also aim to assess the involvement of the TRPV1 receptor by evaluating the possible release of neuropeptides in the esophageal mucosa.

Study design

The study design is a randomized, cross-over study with two different interventions (capsaicin/control infusion) in healthy volunteers.

Intervention

Capsaicin infusion and control infusion.

Study burden and risks

The subjects will perceive mild discomfort during the placement of the infusion catheter. During the infusion period with capsaicin, subjects may perceive some degree of heartburn, retrosternal pain, epigastric burning or nausea. These symptoms will subside quickly after terminating the infusion. Allergies for capsaicin will be actively inquired during screening. No side effects are expected with the infusion of the control solution.

Endoscopy with biopsy taking
During endoscopy with biopsy taking, there is a small risk of perforation or bleeding. Side effects from upper endoscopy are uncommon. Patients might have a slightly sore throat after the procedure and air may be trapped in the stomach causing a bloated feeling. These complaints usually clear up quite quickly after the procedure.

Finally, participation takes time. We estimate that subjects will have to invest 4 hours to participate.

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

Healthy subjects
I. No history of gastrointestinal disease, especially gastro-esophageal reflux disease.
II. BMI <= 18-25 kg/m²
III. Caucasian race
IV. Subject signed the informed consent form and is able to adhere to study protocol

Exclusion criteria

Healthy subjects
I. Age <18 years
II. Erosive esophagitis or gastric ulceration during endoscopy on PPI in the past or during the experiment.
III. Use of regular (> 1 x per week) dietary capsaicin or red pepper containing foods.
IV. Use of medication affecting GI function (prokinetics) or antisecretory medication (PPI) within 3 days prior to endoscopy.
V. Multisystem diseases (including severe cardiopulmonary disease, collagen diseases, coagulation disorders)
VI. Esophageal motility disorders
VII. Previous esophageal or gastric surgery
VIII. Use of anticoagulants or a history of coagulopathy
IX. Pregnancy
X. History of alcohol abuse or current excessive alcohol consumption (> 2 alcoholic beverages per day or > 14 alcoholic beverages per week).
XI. No allergies for capsaicin.

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	05-11-2015
Enrollment:	13
Type:	Actual

Ethics review

Approved WMO Date:	23-07-2015
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	04-04-2016
Application type:	Amendment
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	NL51999.068.15