The effect of capsaicin and cinnamaldehyde on intestinal permeability, gallbladder motility and satiety

Published: 27-10-2010
Last updated: 03-05-2024

To obtain more information about the effects of capsaicin and cinnamaldehyde on the intestine, these substances will be infused directly in the duodenum. Hereafter, the permeability of the intestine, gallbladder motility and the effects on satiety…

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

Summary

ID

NL-OMON34052

Source
ToetsingOnline

Brief title
Capsaicine protocol

Condition

- Gastrointestinal motility and defaecation conditions

Synonym
gallbladder motility, leaky gut

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit Maastricht

Source(s) of monetary or material Support: TIFN

Intervention

Keyword: gallbladder motility, intestinal permeability, nutrients, satiety

Outcome measures

Primary outcome

The primary aim is to assess intestinal permeability by means of sugar

permeability test

Secondary outcome

Secondary outcomes of the study are to assess tight junction functionality in

duodenal biopsy specimens and to assess gallbladder motility and effects on

satiety.

Study description

Background summary

An altered permeability has been proposed to play an important role in the pathogenesis of several gastrointestinal disoders, such as irritable bowel syndrome and inflammatory bowel disease. Nutrients derived from food are able to influence the permeability of the intestine and can therefore also affect gastrointestinal symptoms. In this study, we will investigate the effects of capsaicine and cinnamaldehyde, which can be found in hot peppers and cinnamon, respectively, on gastrointestinal physiology.

Study objective

To obtain more information about the effects of capsaicin and cinnamaldehyde on the intestine, these substances will be infused directly in the duodenum. Hereafter, the permeability of the intestine, gallbladder motility and the effects on satiety will be assessed.

Study design

This study is a single-blind placebo-controlled study.

Intervention

Duodenal infusion of capsaicin / cinnamaldehyde / saline (placebo)

Study burden and risks

The substances used in this study are constituents of nutritional products. The known side-effects are nausea, burning sensation and abdominal pain. Should these symptoms occur, they are expected to disappear within a few hours. During vena puncture, volunteers might get a small blue spot.
The posiition of the nasoduodenal tube will be controlled by rontgen fluoroscopy. Radiation during a fluoroscopy is equal to 10% of the annual background radiation. Gastroduodenoscopy is used in everyday clinical practive and is considered safe. The risk for perforation is 0.03% percent.

Contacts

Public
Universiteit Maastricht

P.O. Box 616
6200 MD
NL
Scientific
Universiteit Maastricht

P.O. Box 616
6200 MD
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Elderly (65 years and older)

Inclusion criteria

1) Based on medical history and previous examination, no gastrointestinal complaints can be defined.
2) Age between 18 and 65 years
3) BMI between 20 and 30 kg/m2

Exclusion criteria

1) History of severe cardiovascular, respiratory, urogenital, gastrointestinal/ hepatic, hematological/immunologic, HEENT (head, ears, eyes, nose, throat), dermatological/¬connective tissue, musculoskeletal, metabolic/nutritional, endocrine, neurological/¬psychiatric diseases, allergy, major surgery and/or laboratory assessments which might limit participation in or completion of the study protocol. The severity of the disease (major interference with the execution of the experiment or potential influence on the study outcomes) will be decided by the principal investigator.
2) Use of medication, including vitamin supplementation, except oral contraceptives, within 14 days prior to testing
3) Administration of investigational drugs or participation in any scientific intervention study which may interfere with this study (to be decided by the principle investigator), in the 180 days prior to the study
4) Major abdominal surgery interfering with gastrointestinal function (uncomplicated appendectomy, cholecystectomy and hysterectomy allowed, and other surgery upon judgement of the principle investigator)
5) Dieting (medically prescribed, vegetarian, diabetic, macrobiological, biological dynamic), pregnancy, lactation
6) Excessive alcohol consumption (>20 alcoholic consumptions per week)
7) Smoking
8) Blood donation within 3 months before the study period
9) Self-admitted HIV-positive state

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Allocation:	Randomized controlled trial

Masking:	Single blinded (masking used)
Control:	Placebo
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	03-03-2011
Enrollment:	15
Type:	Actual

Ethics review

Approved WMO

Date:	27-10-2010
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
ClinicalTrials.gov	NCTnummervolgt
CCMO	NL32963.068.10