The effect of ethanol on intestinal permeability and integrity in healthy individuals

Published: 10-09-2009
Last updated: 04-05-2024

The study aims to investigate the effects of moderate ethanol drinking on the intestinal permeability and the tight junction complex. If there increase in the intestinal permeability, these effects will be investigated at molecular level.

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

Summary

ID

NL-OMON33245

Source
ToetsingOnline

Brief title
Ethanol and intestinal permeability

Condition

- Gastrointestinal motility and defaecation conditions

Synonym
increased permeabiliy, leaky gut syndrome

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit Maastricht
Source(s) of monetary or material Support: Top Institute Food and Nutrition;Wageningen

Intervention

Keyword: ethanol, integrity, permeability, tight junction

Outcome measures

Primary outcome

The primary outcome is to assess the small intestinal permeability by means of

sugar permeability testing after intraduodenal administration of ethanol.

Secondary outcome

The secondary outcomes are assessing tight junctions structure in the biopsy

specimens, measuring serum and mucosal ethanol and acetaldehyde concentrations.

Ex vivo determination of the effect of ethanol and acetaldehyde on tight

junction functionality using Ussing chambers

Study description

Background summary

Alcohol consumption is a major health problem worldwide. It affects all systems of the body especially the gastrointestinal tract. Acute or chronic alcohol consumption has deleterious effects on the gastrointestinal mucosa vary from increased intestinal permeability, structural changes to sever destruction of the epithelial lining cells. Human data are still limited and most of the studies were performed in chronic alcohol abusers.

We hypothesize that moderate alcohol drinking also may increase small intestinal permeability and contribute to the subsequent disruption of the tight junction complex. This study may provide more insight into the effects of moderate alcohol drinking on the small intestinal permeability.

Study objective

The study aims to investigate the effects of moderate ethanol drinking on the intestinal permeability and the tight junction complex. If there increase in the intestinal permeability, these effects will be investigated at molecular

level.

Study design

This study is a placebo-controlled study.

Intervention

During this study, alcohol will be administered intraduodenally to induce changes in the intestinal permeability. The exact dose of ethanol will be determined in the pilot study

Study burden and risks

The possible risks in the study are related to the effects of ethanol on the nervous system such nausea , vomiting and euphoria. There are also possible risks related to the intervention with the gastroduodenoscope e.g the risks of bleeding at the site of the biopsy and perforation of the viscera.

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

- Signed informed consent
- Male gender
- Age between 18 and 45 years
- Normal medical history and physical examination
- Normal liver function tests
- Caucausian ethnicity
- BMI between 18 and 30

Exclusion criteria

- History of gastrointestinal disorders or abdominal surgery (uncomplicated appendectomy and cholecystectomy allowed, other surgery upon judgement of the principal investigator)
- History of alcohol abuse or current excessive alcolhol consumption (>2 alcoholic beverages per day or >14 alcoholic beverages per week)
- Recent or chronic medications that may interact with ethanol metabolism or intestinal permeability
- Smoking

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):	15-03-2010
Enrollment:	17
Type:	Actual

Ethics review

Approved WMO

Date:	10-09-2009
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
CCMO	NL27994.068.09