Effects of a butyrate enema on systemic concentrations of short chain fatty acids

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Ethical review	Approved WMO
Status	Recruiting
Health condition type	Benign neoplasms gastrointestinal
Study type	Interventional

Summary

ID

NL-OMON32250

Source
ToetsingOnline

Brief title
Effects of butyrate enema on systemic SCFA concentrations

Condition

- Benign neoplasms gastrointestinal
- Hepatic and hepatobiliary disorders

Synonym
livermetastasis, pancreascarcinoma

Research involving
Human

Sponsors and support

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

Intervention

Keyword: butyrate enema, interorgan metabolism, short chain fatty acids, systemic concentrations

Outcome measures

Primary outcome

short chain fatty acid concentrations in portal, mesenteric, arterial and

hepatic venous blood. From these data we can calculate the role of the liver,

large and small intestine and the spleen in SCFA metabolism.

Secondary outcome

nvt

Study description

Background summary

Short chain fatty acids (mainly butyrate, acetate, and propionate) are produced in the large intestine by bacterial fermentation of undigested carbohydrates, such as dietary fibres. Butyrate is an important energy source of the intestinal epithelium and has a pivotal role in the regulation of epithelial cell proliferation and differentiation, immune function and mucosal protection. Non-digestible carbohydrates (prebiotics) increase the concentrations of colonic butyrate, which has been proposed to be responsible for their beneficial effects. Furthermore, butyrate has been proven to be effective in the treatment of active ulcerative colitis, diversion colitis, short bowel syndrome and pouchitis.
In the present study, the interorgan metabolism of short chain fatty acids will be studied, with special interest in butyrate metabolism. Patients undergoing upper abdominal surgery were chosen as study population and will receive a butyrate enema during surgery. After administering this enema, portal, arterial and hepatic venous SCFA concentrations will be measured in plasma. This study population has been chosen, because the required blood vessels are accessible during this type of surgery. The design used to study the effects of butyrate administration will be an interventional design. Butyrate is generally not a dietary ingredient itself, but is mainly produced after the ingestion of dietary fibre, and as it will be given to patients using a rectal enema, this study is listed as a pharmaceutical trial. The EudraCT number issued for this

study is: 2008-000158-11.

Study objective

In the present study the effects of the colonic administration of butyrate on portal, hepatic, mesenteric venous and arterial SCFA concentrations will be studied in patients undergoing major upper abdominal surgery. The aim is to clarify the interorgan metabolism of short chain fatty acids in human beings.

Study design

Three patient groups, butyrate enema, placebo and controls, will be studied. We first want to test the effects of the vehiculum (60 ml enema without butyrate) in 5 patients, because there might be the possibility of dilution of SCFA already present in the sigmoid and as a result increased absorption might occur. The butyrate enemas will be used in 10 patients and another 5 patients will serve as controls, in which no intervention is done.

Intervention

patients receive either a butyrate enema, placebo or serve as control group.

Study burden and risks

According the blood sampling: The methods applied (intra-abdominal blood sampling) have been used without any problems for the surgical procedure or the patients (MEC 02-045, MEC 03-032, MEC 06-2067) and as published by Van de Poll et al [17].
According to the enema: Enemas are clinically used for several purposes, for example to remove faeces when an individual is constipated, to cleanse the rectum as preparation for an endoscopic examination, or to administer drugs or analgetic agents. Enemas differ greatly in volume (3 ml - 1 L) depending on the area of the colon that has to be reached by the fluid. In the present study 60 ml enemas will be used. In a prior study this relatively small volume was easily tolerated (MEC 04 127). Another study using enemas of 100 ml in patients with Ulcerative Colitis also reported no irritation or consecutive bowel movements or other side effects due to the enema

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

• Patients undergoing major upper abdominal surgery, i.e. partial hepatectomy or pylorus preserving pancreactico duodenectomy.
• Normal liver function, i.e. AST within normal range
• Stable western diet
• Age > 18 years old
• Written informed consent

Exclusion criteria

• Ileo- or colostomy
• Parenchymal or inflammatory liver disease
• Steroid hormone medication
• Lactation, pregnancy
• Inflammatory bowel disease
• Inborn errors of metabolism (liver enzyme deficiencies)
• Excessive drinking (>20 alcoholic consumptions per week)
• Smoking
• Use of antibiotics during and 3 months prior to the study

• Probiotic use during and 2 weeks prior to the study

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Placebo
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	23-06-2009
Enrollment:	20
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	sodium butyrate special quality
Generic name:	sodium butyrate special quality

Ethics review

Approved WMO Date:	05-02-2008
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	24-12-2008

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
EudraCT	EUCTR2008-000158-11-NL
CCMO	NL21692.068.08
Other	volgt