Improving enteral drug delivery with low molecular weight alginate oligosaccharides

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This study will assess whether alginate oligomers enhance the efficacy of anti-diarrheals, i.e. compounds that block intestinal ion and water secretion.

Ethical review	Approved WMO
Status	Pending
Health condition type	Gastrointestinal infections
Study type	Observational invasive

Summary

ID

NL-OMON50130

Source
ToetsingOnline

Brief title
Alginate Drug Delivery

Condition

- Gastrointestinal infections

Synonym
secretory diarrhea; traveller's diarrhea

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Ministerie van OC&W,Bedrijf: AlgiPharma AS (www.algipharma.com)

Intervention

Keyword: intestinal mucosa, secretory diarrhea

Outcome measures

Primary outcome

IC50 values of test compounds for inhibition of the ICM response of rectal

biopsies.

Secondary outcome

IC50 values of test compounds for inhibition of the ICM response in intestinal

cell cultures (organoids).

Histology of biopsies. Gene expression.

Study description

Background summary

Accumulation of mucus on the epithelial surface can block the uptake of small-molecule compounds by the intestinal mucosa, reducing the efficacy of enterally applied drugs (like anti-diarrheals). We hypothesize that measures which reduce mucus accumulation and/or -viscosity, will enhance drug uptake and efficacy

Study objective

This study will assess whether alginate oligomers enhance the efficacy of anti-diarrheals, i.e. compounds that block intestinal ion and water secretion.

Study design

Rectal biopsies will be obtained from healthy volunteers. The effect of the alginate oligomers on the efficacy of a small-molecule blocker of intestinal ion and water secretion will be tested, ex vivo, in the rectal biopsies and organoids made thereof.

Study burden and risks

The procedure to obtain rectal biopsies can be completed within 20 minutes. Including anamnesis, the whole
procedure will take about 45 min. Tissue sampling is virtually painless, although accompanied sporadically with the
loss of minute quantities of blood. The procedure is regularly performed for screening and research purposes in the
context of Hirschsprung*s disease and cystic fibrosis. From this practice, it can be deduced that the risk of serious
adverse effects is negligible.
No benefits are associated with participation.

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

Aged 18-55.
Enrollment by informed written consent

Exclusion criteria

Coagulation disorders
Use of anticoagulants.
(Chronic) constipation. (As this may indicate aberrant intestinal ion and fluid transport.)

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-10-2020
Enrollment:	28
Type:	Anticipated

Ethics review

Approved WMO

Date:	12-08-2020
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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	NL73623.078.20