FAME study: Fecal Administration for eradication of Multiresistant ESBL producing bacteria in carriers

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The objective of the study is to see whether donor feces infusions can help to eradicate ESBL in patients who carry ESBL.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Ancillary infectious topics
Study type	Interventional

Summary

ID

NL-OMON41318

Source
ToetsingOnline

Brief title
FAME trial

Condition

- Ancillary infectious topics

Synonym
carriage of multiresistent bacteria, ESBL carriage

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: VENI Max Nieuwdorp

Intervention

Keyword: carriage, donor feces infusion, elimination, ESBL

Outcome measures

Primary outcome

The outcome and primary study parameter of the study is eradication of ESBL,

from feces, urine and rectum.

This wil be measured on four days following infusion, and subsequently one,

two, four and 12 weeks following donor feces infusion.

Secondary outcome

The secondary outcome is antibioc use in the 12 weeks following infusion, the

total amount of infections in the follow up period of twelve weeks and the

composition of the intestinal flora.

Study description

Background summary

In the Netherlands (and the rest of the world), many patient carry ESBL producing bacteria in their bowel, in their urine or on their skin, following admission to a hospital. These ESBL producing bacteria are not susceptible for the routine antibiotics, and can only be treated with a limited arsenal of (expensive) antibiotics. There are no current techniques or treatment strategies to treat carriage of ESBL carrying patients. These patients are at risk to get new infections with their ESBL producing bacteria, and furthermore, they can infect other patients. PAtients tend to carry ESBL producing bacteria for a prolonged period of time after discharge from a hospital.
There is a clear benefit if elimination of ESBL producing carriage can be achieved.

Donor feces infusion, where feces from a healthy screened donor is infused in the bowel of a patient has been succesfully applied in patients with recurrent intestinal infections.

Study objective

The objective of the study is to see whether donor feces infusions can help to eradicate ESBL in patients who carry ESBL.

Study design

open, prospective non randomised trial. Proof of principle concept, without use of a control group, given de nature of the intervention, the population and the lack of suitable alternative therapies.

Intervention

Patients will be prepared with a laxative drink, on the day prior to the donor feces infusion. On the day of the donor feces infusion, a duodenal tube is positioned. Subsequently donor feces is infused in the tube, prepared from feces from a healthy, througly screened donor.

Study burden and risks

A donor feces infusion can be separated in three procedures,

1 on the day prior to the investigation, a laxative is taken. This carries no risk, but patients consider this a nuisance because of the diarrea it generates.
2 Positioning of the tube in the duodenum carries a theoretical risk of malpositioning of the tube. This is a risk that can be considered extreme rare.
3 Infusing donor feces through a duodenal tube: one risk is vomiting, which we try to minimize to position the tube in the duodenum (instead of for instance the stomach), furthermore we try to reduce the risk by excluding patients with diminshed bowel passage.
The other risk is transmitting and infectious or otherwise contractable disease by infusing donor feces. We try to minimize the risk by using healthy screened donors, who first fill in a questionnaire, followed by a thorough screening of blood and feces (see protocol paragraph 4.1.1 and .6.2)

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

ESBL carriage demonstrated in stool, rectum, perineum or urine
able to give informed consent
Life expectancy of three months or more

Exclusion criteria

1. (Expected) prolonged compromised immunity due to high dose prednisolone, recent cytotoxic chemotherapy for a malignancy, or HIV infection with a CD4 count < 350 cells/L
2. Ileus or signs of diminished bowel passage, or altered anatomical situation which prohibits normal passage of a donor feces infusion
3. Admission to intensive care or vasopressive dependency at time of inclusion
4. Known food allergy to peanuts, wheat, tree nuts, shellfish, fish, milk, sesame, chickpeas or eggs, or other dietary factors that could be accidentally infused with a donor feces infusion.

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	30-05-2013
Enrollment:	10
Type:	Actual

Ethics review

Approved WMO Date:	06-03-2013
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	21-01-2015
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	03-09-2015
Application type:	Amendment
Review commission:	METC Amsterdam UMC

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	NL43141.018.13