

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

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<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruitment stopped
<b>Health condition type</b>	Ancillary infectious topics
<b>Study type</b>	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 will 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 antibiotic 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 patients 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 successfully 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, throughly 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 diarrhea 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 diminished 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**

### **Public**

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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**

<b>Register</b>	<b>ID</b>
CCMO	NL43141.018.13