# Fecal Microbiota Transplantation for eradication of Vancomycin-resistant Enterococci (FAVOR): a pilot study

Published: 18-05-2018
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To assess the impact of FMT on detectable intestinal carriage (by stool culture) of VRE in a 12 month follow-up period.

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| **Ethical review** | Approved WMO |
| **Status** | Will not start |
| **Health condition type** | Bacterial infectious disorders |
| **Study type** | Interventional |

## Summary

### ID

NL-OMON46675

**Source**
ToetsingOnline

**Brief title**
Fecal Microbiota Transplantation for eradication of VRE

### Condition

- Bacterial infectious disorders

**Synonym**
Carriage of vancomycin-resistant Enterococ, vancomycin-resistant Enterococ carrier

**Research involving**
Human

### Sponsors and support

**Primary sponsor:** Universitair Medisch Centrum Utrecht
**Source(s) of monetary or material Support:** Vedanta Biosciences, Inc,Vedanta Biosciences;Inc.

## Intervention

**Keyword:** antimicrobial resistance, eradication, fecal microbiota transplant, vancomycine-resistant Enterococ

## Outcome measures

### Primary outcome

The primary endpoint will be intestinal carriage of VRE (absence/presence by

stool culture of VRE) 6 months / 170 - 185 days after intervention

### Secondary outcome

The secondary endpoint will be intestinal carriage of VRE (absence/presence by

stool culture of VRE) 12 months / 355 - 375 days after intervention

# Study description

### Background summary

Antimicrobial resistance is a growing threat for global health as treatment options for drug-resistant bacterial infections are limited. Uncertainty persists about possibilities to eradicate intestinal carriage of drug-resistant bacteria. Patients who are intestinal carriers of Vancomycin-Resistant Enterococcus may attain subsequent infections with few treatment options. Elimination of such carriage is therefore of clinical interest. Fecal Microbiota Transplantation (FMT) is increasingly used for the treatment of recurrent Clostridium difficile infections in humans and evidence is growing that FMT could also be an approach to restore a healthy intestinal microbiota to clear VRE colonization.

### Study objective

To assess the impact of FMT on detectable intestinal carriage (by stool culture) of VRE in a 12 month follow-up period.

### Study design

Prospective, open-label, observational pilot study

## Intervention

Fecal microbiota transplantation: Bowel lavage, followed by administering feces suspension (obtained from te Nationale Donor Feces Bank), via a duodenal tube.

## Study burden and risks

The burden for participants consists of 6 hospital visits, the bowel lavage, the FMT procedure, the collection of feces during the follow-up period and at least 2 telephone appointments. If the patient is not able to come to the hospital, 5 out of 6 hospital visits can be exchanged for a home visit by the investigator, with exception of Visit 2 (FMT).

Hospital visits:
1. Screening visit (SV): study is proposed (at outpatient clinic or via telephone appointment), one fecontainer will be handed out.
2. Visit 0 (V0): Signing informed consent at outpatient clinic or at patient's home and collection of baseline data (history and physical examination, collecting feces for microbiological tests, blood exam), providing more detailed information about procedures. Scheduling appointments for visit 1 and FMT. Colofort for bowel lavage will be provided to the patient with instructions for use. Fecontainers will be provided.
3. Visit 1 (V1): Telephone appointment The results of the feces and blood samples will be discussed with the patient. Again, all inclusion and exclusion criteria and patient willingness to participate will be checked.
4. Day before visit 2: The patient starts bowel lavage following instructions provided by the research physician.
5. Visit 2 (V2): FMT at outpatient clinic
6. Visit 3 (V3): Telephone appointment at T=1 week, which will consist of history taking and making sure the participant has collected a feces sample which will be sent through courier service to the microbiological laboratory.
7. Visit 4 (V4): Telephone appointment at T=1 month, which will consist of history taking and making sure the participant has collected a feces sample which will be sent through courier service to the microbiological laboratory.
8. Visit 5 (V5): Telephone appointment at T=3 months, which will consist of history taking and making sure the participant has collected a feces sample which will be sent through courier service to the microbiological laboratory.
9. Visit 6 (V6): Appointment at outpatient clinic or at patient's home at T=6 month, which will consist of history taking, collecting a feces sample and a final blood exam.
10. Visit 7 (V7): Telephone appointment at T=12 months, which will consist of history taking and making sure the participant has collected a feces sample which will be sent through courier service to the microbiological laboratory.

The burden of the bowel lavage consists of having to follow specific meal instructions from the evening before FMT and having to refrain from eating the

day of FMT until 2 hours after administering of the feces suspension. A total of 2 litres of the colofort used for bowel lavage has to be ingested following instructions provided by the research physician. These instructions are derived from the NDFB protocol.
The FMT procedure starts with the nasoduodenal tube placement, this may be associated with discomfort. During the insertion the participant may experience gagging and vomiting. Gagging may lead to a sensation of dyspnea and vomiting may be associated with a slight risk of bronchoaspiration and subsequent pneumonia. There is a small risk of perforation of the esophagus or stomach, which may result in mediastinitis.
FMT can be associated with mild adverse events such as cramping, belching and diarrhea.
So far FMT has been reported to be an extremely safe procedure without major adverse effects. The *healthy* stool flora for this procedure will be obtained from by the NDFB (Nederlandse Donor Feces Bank). FMT has been successfully used to treat recurrent infections with a specific pathogen (Clostridium difficile), for which it is considered safe and effective.

The study will examine whether it is possible to eradicate intestinal carriage with VRE by administration of feces suspension obtained from the NDFB, through a tube inserted in the nose and ending in the duodenum. The benefit of participation in this trial is eradication of VRE-carriage and thereby reducing the risk of future infections caused by this bacterium. This benefit outweighs the involved risks.

## 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

Adult patients (*18 years at date of inclusion)
Ability to provide informed consent
Documented intestinal carriage of VRE by stool culture
One of the following:
o Any malignancy with the exception of successfully treated basal cell cancer of the skin
o Any hospital-acquired infection in the past 12 months
o Any type of vascular disease including class I-II congestive heart failure, acute myocardial infarction, (un)stable angina pectoris, percutaneous transluminal coronary angioplasty, coronary artery bypass grafting, aortic aneurysmata, resistant hypertension (defined as blood pressure that remains above 140 mmHg systolic or 90 mmHg diastolic in spite of the concurrent use of 3 antihypertensive agents of a different class)
o Chronic lung disease
o Chronic kidney disease, defined as a decreased kidney function (estimated glomerular filtration rate (CKD-EPI) between 15 ml/min/1.73m2 and 60 ml/min/1.73m2) or kidney damage (including microalbuminuria) for three or more months
o Chronic liver disease
o Cerebrovascular disease including stroke, transient ischemic attack or subarachnoid haemorrhage
o Any haematological disorder
o Any auto-immune disease with the exception of inflammatory bowel disease
o Diabetes mellitus (all types)

## Exclusion criteria

- Difficult / impossible follow-up
- Pregnancy or planned pregnancy or breastfeeding
- Allergy or other contraindication to colofort
- Severe food allergy (anaphylaxis, urticaria)
- Recurrent aspirations / chronic dysphagia or anatomic contraindication to the placement of a nasogastric tube
- Congestive heart failure class III-IV

- Estimated life expectancy < 6 months
- Current hospitalization in an Intensive Care Unit
- Treatment with any systemic antibiotic on the day of inclusion
- Severe immunodeficiency
o Systemic chemotherapy * 30 days from baseline or planned chemotherapy within the next 12 months
o Human Immunodeficiency Virus (HIV) with CD4 count < 250/mcl
o Neutropenia with an absolute neutrophil count <1000/µL
o Hematopoietic stem cell transplant recipients
o Solid organ transplant recipients
- Inflammatory Bowel Disease (Crohn*s disease, Colitis Ulcerosa)
- Estimated glomerular filtration rate (CKD-EPI) < 15 ml/min/1.73m2
- Unavailability of compatible FMT preparation (with regard to donor / recipient CMV and EBV serology)

# Study design

## Design

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| Study phase: | 2 |
| Study type: | Interventional |
| Masking: | Open (masking not used) |
| Control: | Uncontrolled |
| Primary purpose: | Treatment |

## Recruitment

NL

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|---|---|
| Recruitment status: | Will not start |
| Enrollment: | 10 |
| Type: | Anticipated |

# Ethics review

Approved WMO

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| Date: | 18-05-2018 |
| Application type: | First submission |
| Review commission: | METC Universitair Medisch Centrum Utrecht (Utrecht) |

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| Approved WMO Date: | 19-09-2018 |
| Application type: | Amendment |
| Review commission: | METC Universitair Medisch Centrum Utrecht (Utrecht) |

# 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 | NL64076.041.18 |