

Fecal microbiota transplantation against intestinal colonization by multidrug resistant bacteria

Submission date 26/09/2017	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 11/10/2017	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 26/03/2018	Condition category Infections and Infestations	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

Recurrent infections with antibiotic-resistant bacteria are a major health problem as they are associated with increased hospitalization, medication costs and mortality (death). The aim of this study is to treat patients carrying antibiotic-resistant bacteria with a fecal transplant from a donor.

Who can participate?

Patients carrying enterobacteriaceae with extended-spectrum beta lactamase (ESBL-EB)

What does the study involve?

Rectal swabs are taken at the start of the study and 1 week before the fecal transplantation. The fecal solution is administered through a tube into the small intestine. The treatment takes about 30 minutes with an observation period of 1 to 3 hours. Rectal swab samples are collected at 1, 2 and 4 weeks follow-up. Fecal samples are taken for bacterial analysis before the fecal infusion and at 4 weeks follow-up.

What are the possible benefits and risks of participating?

Participants may benefit from being free of antibiotic-resistant bacteria, so that when infection occurs this should be easier to cure with antibiotics. The risks are discomfort, nausea, and a small chance of infection despite proper donor testing.

Where is the study run from?

Academic Medical Centre (Netherlands)

When is the study starting and how long is it expected to run for?

January 2013 to April 2016

Who is funding the study?

1. Dutch Kidney Foundation
2. Netherlands Organisation for Health Research and Development
3. Netherlands Organisation for Scientific Research

Who is the main contact?

Pieter de Groot
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Contact information

Type(s)

Public

Contact name

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Additional identifiers

Protocol serial number

FAME 2013_003

Study information

Scientific Title

Fecal microbiota transplantation against intestinal colonization by extended spectrum beta-lactamase producing Enterobacteriaceae

Acronym

FAME

Study objectives

Fecal microbiota transplantation can reverse colonization by multidrug resistant intestinal bacteria.

Ethics approval required

Old ethics approval format

Ethics approval(s)

The ethics committee of the Academic Medical Center (Amsterdam) (MEC-AMC), 06/03/2013

Study design

Uncontrolled single-center clinical trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Extended spectrum beta-lactamase producing Enterobacteriaceae carriage

Interventions

Rectal swabs were taken at the moment of inclusion and <1 week before the fecal transplantation. Fecal solution was administered by duodenal tube which was placed by CORTRAK-technology, treatment duration (fecal infusion) lasted about 30 minutes with an observation period of 1 to 3 hours. Rectal swab follow-up samples were collected at 1, 2 and 4 weeks follow-up. Fecal samples for microbiota analysis were taken before fecal infusion and at 4 weeks follow-up.

Intervention Type

Procedure/Surgery

Primary outcome(s)

Negative cultures for ESBL, assessed with MALDI-TOF MS using the Bruker Biotyper (Bruker Daltonics, Germany) and antimicrobial susceptibility testing performed using the VITEK2 system (bioMérieux). Rectal swabs taken at 0, 1, 2, 4 weeks

Key secondary outcome(s)

Fecal microbiota analyzed by human intestinal tract (HIT-)chip from samples taken at 0 and 4 weeks

Completion date

11/04/2016

Eligibility**Key inclusion criteria**

Patients carrying enterobacteriaceae with extended-spectrum beta lactamase (ESBL-EB) on two consecutive cultures, one of which at most 1 week before fecal microbiota transplantation (FMT)

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Key exclusion criteria

Severe immunodeficiency

Date of first enrolment

30/05/2013

Date of final enrolment

11/04/2016

Locations**Countries of recruitment**

Netherlands

Study participating centre**Academic Medical Centre**

Meibergdreef 9

Amsterdam

Netherlands

1105AZ

Sponsor information**Organisation**

Academic Medical Center

ROR

<https://ror.org/03t4gr691>

Funder(s)**Funder type**

Government

Funder Name

Nierstichting

Alternative Name(s)

Dutch Kidney Foundation

Funding Body Type

Private sector organisation

Funding Body Subtype

Trusts, charities, foundations (both public and private)

Location

Netherlands

Funder Name

ZonMw

Alternative Name(s)

Netherlands Organisation for Health Research and Development

Funding Body Type

Private sector organisation

Funding Body Subtype

Other non-profit organizations

Location

Netherlands

Funder Name

Nederlandse Organisatie voor Wetenschappelijk Onderzoek

Alternative Name(s)

Netherlands Organisation for Scientific Research, Dutch National Scientific Foundation, Dutch National Science Foundation, Dutch Research Council (Nederlandse Organisatie voor Wetenschappelijk Onderzoek), NWO:Nederlandse Organisatie voor Wetenschappelijk Onderzoek, Nederlandse Organisatie voor Wetenschappelijk Onderzoek (NWO), Dutch Research Council, The Dutch Research Council (NWO), Dutch Research Council, Netherlands, NWO

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

Netherlands

Results and Publications

Individual participant data (IPD) sharing plan

SPSS and Excel databases and R-code will be available upon request to p.f.degroot@amc.nl or m.nieuwdorp@amc.nl. Data will be shared by e-mail. Data is fully anonymized and meets the criteria of the ethics review board.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	22/03/2018		Yes	No