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Fecal microbiota transplantation against intestinal colonization by multidrug resistant bacteria

Submission date
26/09/2017

Recruitment status
No longer recruiting

Registration date
11/10/2017

Overall study status
Completed

Last Edited
26/03/2018

Condition category
Infections and Infestations

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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?
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Contact information

Type(s)
Public

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Non randomised study

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied
Extended spectrum beta-lactamase producing Enterobacteriaceae carriership

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 measure
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

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

Overall study start date
01/01/2013

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

Age group
Adult

Sex
Both

Target number of participants
15

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

Sponsor details
Meibergdreef 9
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Sponsor type
Hospital/treatment centre

Website
www.amc.nl

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, Dutch Research Council, Netherlands, NWO

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Netherlands

Results and Publications

Publication and dissemination plan
The trialists intend to publish as soon as the study is registered.

Intention to publish date
31/12/2017

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