Feasibility analysis of nasoduodenal feces administration to eradicate resistant enterobacteriaeceae.

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Primary objective is to investigate if donor feces infusion is effective in eradication of ESBL producing Enterobacteriaceae in the large intestine. Secondary objective is to determine whether ESBL decolonisation of the large intestine actually…

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON38475

Source
ToetsingOnline

Brief title
FANFARE

Condition

- Other condition
- Bacterial infectious disorders
- Renal disorders (excl nephropathies)

Synonym
ESBL urinary tract infections and ESBL colonisation

Health condition

nierfalen waarvoor niertransplantatie

Research involving

Human

Sponsors and support

Primary sponsor: Academisch medisch centrum
Source(s) of monetary or material Support: Innovatiebeurs van de nierstichting

Intervention

Keyword: Colonisation, ESBL, Feces, Transplantation

Outcome measures

Primary outcome

Primary outcome is ESBL decolonisation of the rectum after 12 weeks post donor

feces infusion.

Secondary outcome

1: Development of ESBL related urinary tract infection within 24 weeks

follow-up time after donor feces infusion.

2: Changes in microbiome prior and after donor feces infusion.

Study description

Background summary

Among renal transplant recipients urinary tract infections (UTIs) and especially UTIs with tissue invasion such as transplant pyelonephritis and urosepsis are a major cause of graft deterioration, prolonged hospitalization and patient morbidity. They also lead to antimicrobial resistance resulting from repeated antibiotic use. Most concerning are the Extended-Spectrum Beta-Lactamase (ESBL) producing Enterobacteriaceae, which have gained the ability to hydrolyse extended-spectrum beta-lactam antibiotics such as ceftriaxone. The latter is commonly used in the treatment of UTIs among renal transplant recipients. Frequent exposure to beta-lactam antibiotics leads to colonization of the gastrointestinal tract by ESBL producing enterobacteriaeceae, which may persist for many years and is associated with (recurrent) ESBL related infections of the urogenital tract. The majority of these infections are caused by the same ESBL producing enterobacteriaeceae as

those found in the feces of the patient.
The incidence of UTIs caused by ESBL producing Enterobacteriaceae has dramatically increased over the last few years. ESBL related UTIs tend to re-occur and require treatment with long term intravenous meropenem, risking the development of carbapenem resistance. Therefore the development of an ESBL decolonization scheme will be a cornerstone in the prevention of ESBL related UTIs in renal transplant recipients.

Donor feces infusion has been demonstrated to be effective against recurrent Clostridium difficile infections. In this current study we want to investigate whether donor feces infusion is also effective in clearing ESBL producing Enterobacteriaceae residing in the large intestine of renal transplant recipients.

Study objective

Primary objective is to investigate if donor feces infusion is effective in eradication of ESBL producing Enterobacteriaceae in the large intestine.

Secondary objective is to determine whether ESBL decolonisation of the large intestine actually leads to decreased incidence of ESBL related urinary tract infection within 24 weeks follow-up after donor feces infusion.
Secondary objective is also the evaluation of the infuence of donor feces infusion on the microbiome.

Study design

The aim of this study is to perform a single center, single cohort, non-randomised, proof of principle study about donor feces infusion in 10 renal transplant recipients colonised by ESBL producing Enterobacteriaeceae in the large intesine.
Renal transplant recipients who were known to be carriers of ESBL producing Entereobacteriaeceae in 2012 will be recruited. ESBL culture of the rectum, urine and throat will be performed. If the recipient is at least ESBL positive in the rectum, inclusion will take place. It might be possible that besides the rectum, ESBL producing Enterobacteriaceae are also present in the urine and/or throat. These two site will be decolonized with chlorhexidine mouth rinse and nitrofurantoin respectively. When eventually the rectum remains ESBL positive, donor feces infusion will take place. Diet inventory will also be made of each subject via a questionnaire.
Prior to donor feces infusion, a feces sample of the subject will be taken and stored for microbiome analysis.
The intervention is donor feces infusion. At 4 time points after donor feces infusion (1, 2, 4 and 12 weeks) cultures will be taken of the rectum, urine and the throat. Feces samples will also be collected anda stored at these 4 time points for microbiome analysis. Each subject will be followed for 24 weeks

after donor feces infusion for development of ESBL related urinary tract infection.

Intervention

Donor feces infusion.

Study burden and risks

Prior to inclusion, diet pattern will be investigated via questionnaire.
Recipients may experience colon lavage and insertion of nasoduodenal tube as inconvenient. There is a theoretical risk of malpositioning of the tube (for example in the lungs): this risk is considered to be extremely rare.
Main side effects of donor feces infusion are abdominal cramps, diarrhoea and nausea which resolve within few days after donor feces infusion. Infusion of feces might cause vomiting, however this risk is reduced by positioning the tube in the duodenum instead of the stomach. Furthermore, patients with diminished bowel passage will be excluded. Risk of contagious diseases through feces will be kept low as possible by throughout screening of healthy feces donors by questionnaires and laboratory examination.
Other adverse influences of donor feces infusion in immunecompromised patients is unknown, however 2 renal transplant recipients have undergone succesfully donor feces infusion against recurrent Clostridium difficile infections without serious adverse events.

Subjects who underwent donor feces infusion have to be cultured five times (prior to donor feces infusion and at week 1, 2, 4 and 12 after donor feces infusion). Furthermore, they also have to collect samples of their feces at these time points.

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

Renal transplant recipients colonised by ESBL producing Entrobacteriaceae in the large intestine.
Stable renal allograft function with maintenance dose of immunosuppressive therapy.
No food allergies.

Exclusion criteria

1: Patients with ESBL strain in urine which is resistant to first line antibiotics (as nitrofurantoin)
2: Patients still being ESBL positive in throat or urine despite pre-treatment with chlorhexidin or first line antibiotic (as nitrofurantoin).
3: Experiencing rejection episode which require high dose immune-suppressants or critically ill recipients admitted to the ICU.
4: Signs of diminished bowel passage or ileus
5: Recent endoscopy with biopsies within last three months
6: Pregnancy
7: Known food allergie to any kind of food products.
8: Heavily immunocompromised patients (prednisone use of > 60 mg per day or CD4 count < 200 cells/L) or patients who require chemotherapy for active malignancy.

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	30-06-2014
Enrollment:	10
Type:	Actual

Ethics review

Approved WMO

Date:	21-03-2014
Application type:	First submission
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	NL46308.018.13