Safety and tolerability of controlled Human Urine Transfusion for Urinary tract infection Prevention (SHUTUP): a pilot study

Published: 06-04-2017
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To investigate the safety and tolerability of controlled human urine transfusion in female patients with recurrent UTI*s.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Bacterial infectious disorders
Study type	Interventional

Summary

ID

NL-OMON49501

Source
ToetsingOnline

Brief title
Controlled human urine transfusion for UTI

Condition

- Bacterial infectious disorders
- Urinary tract signs and symptoms

Synonym
urinary tract infections AND cystitis

Research involving
Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum

Source(s) of monetary or material Support: Projectgeld NWO

Intervention

Keyword: Safety, Urine transfusion, UTI prevention

Outcome measures

Primary outcome

- Frequency and magnitude of adverse events within 6 months of controlled human urine transfusion, including the occurrence of UTI*s that are possibly, probably or definitely related to the transfusion procedure.

So concrete: total amount of adverse events, serious adverse events and suspected unexpected serieous adverse reactions.

Secondary outcome

- Urine microbiome composition and diversity by total amount of genus, percentage of genus and the Shannon diversity index before and after urine transfusion.
- Time to change (in days) of urine microbiome composition and diversity
- Frequency of UTI*s (in exact amounts) after urine transfusion.

Study description

Background summary

Almost half of all women will experience one UTI during their lifetime. Urinary tract infections (UTIs) are the most common bacterial infections at the general practice, in acute care and in nursing homes. The increasing incidence of resistant enterobacteriaciae poses a threat to the antibiotic treatment of UTI. Following the discovery of the bladder microbiome, it was found that urinary tract infections are associated with a decreased urinary microbiome diversity,

opening up avenues for bacterial interference as alternative strategies to antibiotic treatment.
We hypothesize that instillation of the bladder with a polymicrobial inoculum will increase the bladder microbiota diversity in patients with recurrent UTI*s and as such may increase the beneficial effects of bacterial interference. In addition, we believe that urine from healthy donors potentially may be the most suitable inoculum for long lasting colonization of the bladder epithelium.

Study objective

To investigate the safety and tolerability of controlled human urine transfusion in female patients with recurrent UTI*s.

Study design

This will be a prospective, open label pilot clinical trial.

Intervention

Two transfusions of 100 ml of urine within 5 days by transurethral catheterization after an antibiotic free interval of 3 days.

Study burden and risks

Patients with recurrent UTI*s will be recruited from the general practice and from the infectious diseases outpatient department and offered transfusion after an antibiotic free interval of 3 days. Blood, urine and faeces samples will be taken at the screening visits. The urine transfusion procedure will be performed twice within 5 days through transurethral catheterization. Recipients will visit the trial centre at day 3 after the last transfusion, weekly for 4 weeks and after 3 and 6 months. Urine sampling by voided urine will take place at every visit. Urine collected by transurethral catheterization will take place on both transfusion days and 1 week and 1 month after the urine transfusion. Urethral swaps will be done twice for patients. Two other patient faeces samples will be collected 1 week and 1 month after transfusion.
Patients may experience adverse events following TUC, such as catheter-associated UTI. However, the chance on developing an catheter-associated UTI after single catheterization is small and estimated around 1-5%. A cystitis after catheterization is mostly a harmless condition with a conservative approach. In case of an UTI during the follow-up patients will be treated with antibiotics according to standard of care.
Trauma related to the transurethral catheterisation, such as urethra, bladder or rectum injury are very rare if performed by a skilled nurse or physician.
Potential adverse events during the urine transfusions can be: bladder spasms, (lower) abdominal pain, and transfusion of resistant micro-organisms. For the latter, donors got screened for potential carriage of resistant

micro-organisms. .
There is no benefit of participation in this pilot trial for the donors.
Potentially, patients may benefit from participation if the urine transfusion prevents subsequent UTIs.

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

1. Subject is premenopausal, aged * 18 and *45 years
2. Subject had recurrent UTI*s (*3 documented UTI*s in the last year with documented symptom-free interval of at least 2 weeks) following the definition of a urinary tract infection: the presence of significance bacteruria (103 CFU/ml or more), pyuria and fever plus one or more of the following signs and symptoms: suprapubic or flank discomfort, dysuria, bladder spasms or pollakiuria

3. Subject has a documented urinary tract infection (see definition), for which oral antibiotic therapy has been initiated.
4. Subject has adequate understanding of the procedures of the study and agrees to abide strictly thereby.
5. Subject is able to communicate well with the investigators and is available to attend all study visits.
6. Subject has signed informed consent.
7. Subject will remain available during the first 3 weeks of the study period

Exclusion criteria

1. Any history or evidence at screening of clinically significant symptoms, physical signs or abnormal laboratory values suggestive of systemic conditions.
2. 2. Documented vesico-urethral reflux
3. Documented urinary retention > 100 milliliters post-void residual urine
4. Anatomic urogenital abnormalities
5. Urolithiasis
6. Nephrostomy catheters
7. Extraurogenital infections that require prolonged antibiotic therapy
8. Pregnancy
9. Use of probiotics and or cranberry juice
10. Allergy or intolerance for multiple common prescribed antibiotics
11. Carriage of multi drug resistant organisms in faeces and/or urine without regular antibiotic treatment options

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):	15-11-2017
Enrollment:	6

Type:	Actual

Ethics review

Approved WMO Date:	06-04-2017
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	10-07-2017
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	18-10-2019
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

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	NL60330.058.16
Other	volgt