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Non-antibiotic versus Antibiotic Prophylaxis for Recurrent Urinary Tract Infections

Submission date	Recruitment status	[_] Prospectively registered
12/09/2005	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
12/09/2005	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
10/04/2014	Urological and Genital Diseases	

Plain English summary of protocol

Background and study aims
Urinary tract infections (UTIs) are very common infections in women. For women with UTIs which happen more than twice a year, low dose antibiotic prophylaxis (preventative treatment) for several months can be recommended. However, this can lead to resistance of not only the bacteria responsible for the UTI but also of all the natural bacterial found on/in a healthy person. Previous studies have demonstrated that prophylaxis with non-antibiotic compounds (lactobacilli oral therapy) compared with a dummy treatment may lead to a lower number of new UTI episodes. Cranberry juice, compared with a dummy treatment, has also resulted in fewer UTIs in women. This study aims to compare these forms of non-antibiotic prophylaxis to antibiotic prophylaxis.

Who can participate?
Women who have an indication for prophylaxis of recurrent UTIs.

What does the study involve?
Participants will be randomly allocated to one of four treatments. In study A, 280 pre-menopausal women will receive either cranberry capsules or standardized antibiotic treatment. In study B, 280 postmenopausal women will receive either lactobacilli oral therapy or standardized antibiotic treatment.
Each month, during 15 months, all patients have to fill in a short questionnaire and to collect urine, faeces and a vaginal swab. At the beginning of the study and after 6,12 and 15 months they will have to fill in a longer questionnaire about quality of life.

What are the possible benefits and risks of participating?
Not provided.

Where is the study run from?
Academic Medical Center, Amsterdam, the Netherlands.

When is the study starting and how long is it expected to run for?
September 2005 to September 2009

Who is funding the study?
The work was supported by the Netherlands Organization for Health Research and Development

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
Project 6200.0017 (ZonMw); NTR79

Study information

Scientific Title

Acronym
The NAPRUTI-study.

Study objectives
Not provided at time of registration

Ethics approval required
Old ethics approval format

Ethics approval(s)

Ethics approval received from the local medical ethics committee

Study design
Multicentre, randomised, double blinded, active controlled, parallel group trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Urinary tract infections

Interventions
In trial A, 280 pre-menopausal women will receive either cranberry capsules (twice daily 500 mg) or standardised antibiotic treatment (once daily 480 mg trimethoprim-sulfamethoxazole [TMP /SMX]).

In trial B, 280 postmenopausal women will receive either lactobacilli oral therapy (twice daily a capsule with greater than 10^9 Lactobacillus rhamnosus GR-1 and L. reuteri RC-14) or standardised antibiotic treatment (480 mg TMP/SMX).

The double-dummy method is used for blinding. Each patient receives one tablet and two capsules daily, but only one of them (the tablet or the capsules) contains the active substance. All study medication must be taken for the duration of 12 months. During the treatment period and the three months after stopping the treatment (wash-out period), each month patients have to fill in a short questionnaire and collect urine, faeces and a vaginal swab for culturing.

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Cranberry capsule, trimethoprim-sulfamethoxazole, lactobacilli oral therapy

Primary outcome measure
1. The numbers of recurrences of symptomatic UTI
2. Time to first occurrence of antibiotic resistance in urine or faeces

Secondary outcome measures

1. Incidence of other infections
2. Incidence of asymptomatic bacteriuria events
3. Quality of life
4. Costs per prevented UTI

Overall study start date
01/09/2005

Completion date
01/09/2009

Eligibility

Key inclusion criteria
1. Women aged 18 years or older
2. At least three symptomatic urinary tract infections (UTIs), uncomplicated or complicated, in the year preceding study inclusion OR already using any form of prophylaxis to prevent recurrences of urinary tract infections and at least three symptomatic urinary tract infections in the year befort the start of the prophylaxis

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Female

Target number of participants
560

Key exclusion criteria
1. Life expectancy less than or equal to one year
2. Legally incapable
3. A renal transplant in the medical history
4. Contraindications for or relevant interactions with trimethoprim-sulfamethoxazole (TMP/SMX)
5. Additional exclusion criteria for trial A (pre-menopausal women randomised to either cranberry capsules or TMP/SMX):
5.1. Breastfeeding, pregnancy, or pregnancy wish for the next year
5.2. Contraindications for or relevant interactions with cranberries

Date of first enrolment
01/09/2005

Date of final enrolment
01/09/2009

Locations

Countries of recruitment
Netherlands

Study participating centre
Academic Medical Centre
Amsterdam
Netherlands
1105 AZ

Sponsor information

Organisation
Academic Medical Centre (AMC) (The Netherlands)

Sponsor details
P.O. Box 22660
Amsterdam
Netherlands
1100 DD

Sponsor type
Hospital/treatment centre

Website
http://www.amc.nl/

ROR
https://ror.org/03t4gr691

Funder(s)

Funder type
Research organisation

Funder Name
The Netherlands Organisation for Health Research and Development (ZonMw) (The Netherlands)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results of cranberries vs antibiotics	25/07/2011		Yes	No
Results article	results of lactobacilli vs antibiotics	14/05/2012		Yes	No
Results article	results	04/04/2014		Yes	No