Non-antibiotic versus Antibiotic Prophylaxis for Recurrent Urinary Tract Infections.

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON28294

Source
Nationaal Trial Register

Brief title
The NAPRUTI-study.

Intervention

Outcome measures

Primary outcome

1. The numbers of recurrences of symptomatic UTI;

2. Time to first occurrence of antibiotic resistance in urine or faeces.

Secondary outcome

1. Incidence of other infections;

2. Incidence of asymptomatic bacteriuria
events;
3. Quality of life;

4. Costs per prevented UTI.

Study description

Background summary

N/A

Study objective

N/A

Intervention

In trial A, 280 pre-menopausal women will receive either cranberry capsules (twice daily 500 mg) or standardized 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 >10e9 Lactobacillus rhamnosus GR-1 and L. reuteri RC-14) or standardized antibiotic treatment (480 mg TMP/SMX).
The “double-dummy”-method is used for blinding. Each patient receives 1 tablet and 2 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.

Contacts

Public
Academic Medical Center (AMC), Department of Infectious diseases, Tropical Medicine and AIDS,
P.O. Box 22660
Mariëlle Beerepoot
Meibergdreef 9

Amsterdam 1100 DD
The Netherlands
+31 (0)20 5667921
Scientific
Academic Medical Center (AMC), Department of Infectious diseases, Tropical Medicine and

AIDS,
P.O. Box 22660
Mariëlle Beerepoot
Meibergdreef 9

Amsterdam 1100 DD
The Netherlands
+31 (0)20 5667921

Eligibility criteria

Inclusion criteria

1. Women aged 18 years or older;

2. At least 3 symptomatic urinary tract infections, 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 3 symptomatic urinary tract infections in the year befort the start of the prophylaxis.

Exclusion criteria

1. Life expectancy
2. Legally incapable;

3. A renal transplant in the medical history;

4. Contraindications for or relevant interactions with TMP/SMX;

5. Additional exclusion criteria for trial A (pre-menopausal women randomized to either cranberry capsules or TMP/SMX);

6. Breastfeeding, pregnancy, or pregnancy wish for the next year;

7. Contraindications for or relevant interactions with cranberries.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Masking:	Double blinded (masking used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-09-2005
Enrollment:	560
Type:	Anticipated

Ethics review

Positive opinion

Date:	15-07-2005
Application type:	First submission

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
NTR-new	NL49
NTR-old	NTR79

Register	ID
Other	: Project 6200.0017 (ZonMw)
ISRCTN	ISRCTN50717094

Study results

Summary results
N/A