

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

|                                        |                                                              |                                                      |
|----------------------------------------|--------------------------------------------------------------|------------------------------------------------------|
| <b>Submission date</b><br>12/09/2005   | <b>Recruitment status</b><br>No longer recruiting            | <input type="checkbox"/> Prospectively registered    |
|                                        |                                                              | <input type="checkbox"/> Protocol                    |
| <b>Registration date</b><br>12/09/2005 | <b>Overall study status</b><br>Completed                     | <input type="checkbox"/> Statistical analysis plan   |
|                                        |                                                              | <input checked="" type="checkbox"/> Results          |
| <b>Last Edited</b><br>10/04/2014       | <b>Condition category</b><br>Urological and Genital Diseases | <input type="checkbox"/> Individual participant data |

## 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?

NAPRUTI@amc.uva.nl

## Contact information

### Type(s)

Scientific

### Contact name

Dr Mariëlle Beerepoot

### Contact details

Academic Medical Centre

Dep Infectieziekten, tropische geneeskunde en AIDS

P.O. Box 22660

Amsterdam

Netherlands

1105 AZ

+31 (0)20 5667921

M.A.Beerepoot@amc.uva.nl

## Additional identifiers

### Protocol serial number

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

### Primary study design

Interventional

## Study design

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

## Study type(s)

Treatment

## 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(s)

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

## Key secondary outcome(s)

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

## 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 before the start of the prophylaxis

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

18 Years

**Sex**

Female

**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)

## 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

## 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? |
|---------------------------------|----------------------------------------|--------------|------------|----------------|-----------------|
| <a href="#">Results article</a> | results of cranberries vs antibiotics  | 25/07/2011   |            | Yes            | No              |
| <a href="#">Results article</a> | results of lactobacilli vs antibiotics | 14/05/2012   |            | Yes            | No              |
| <a href="#">Results article</a> | results                                | 04/04/2014   |            | Yes            | No              |