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

Gepubliceerd: 15-07-2005 Laatst bijgewerkt: 18-08-2022

N/A

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON28294

Bron
Nationaal Trial Register

Verkorte titel
The NAPRUTI-study.

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

N/A

Doel van het onderzoek

N/A

Onderzoeksproduct en/of interventie

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.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Blindering:	Dubbelblind

Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-09-2005
Aantal proefpersonen:	560
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	15-07-2005
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL49
NTR-old	NTR79
Ander register	: Project 6200.0017 (ZonMw)
ISRCTN	ISRCTN50717094

Resultaten

Samenvatting resultaten
N/A