Cranberries after pelvic floor surgery for urinary tract infection prophylaxis

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Cranberry capsules given peri-operatively reduce the risk of clinical overt urinary tract infection after elective pelvic floor surgery with indwelling catheter postoperatively compared with placebo

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

Samenvatting

ID

NL-OMON21770

Bron
NTR

Verkorte titel
CUTIP trial

Aandoening

urinary tract infection
cranberry
pelvic floor surgery

urineweginfectie
cranberry
bekkenbodemchirurgie

Ondersteuning

Primaire sponsor: Ikazia hospital, Rotterdam (NL)
Department of Obstetrics and Gynaecology
Overige ondersteuning: fund = initiator = sponsor

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Incidence of clinical diagnosis of urinary tract infection within 6 weeks after surgery. There is clinical diagnosis of urinary tract infection when the medical doctor (blinded for investigation arm) diagnoses and treats a urinary tract infection.

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale: One of the most common complications after pelvic floor surgery is an urinary tract infection (UTI), with an estimated risk of 10-64%. Many trials have been performed to reduce this rate. Antibiotics as prophylaxis may reduce the prevalence of UTI’s by 50%, but microbial resistance against antibiotics may be a large disadvantage. Therefor it is desirable to look for other prophylactic options. Recent research found a 50% reduction in rate for UTI with the use of cranberry capsules after elective gynaecology surgery. This suggests that cranberry capsules may serve as a good prophylaxis for UTI’s peri-operatively.

Objective: To assess whether cranberry capsules given peri-operatively reduce the risk of clinical overt UTI after elective pelvic floor surgery with indwelling catheter postoperatively, compared with placebo.

Study design: A single centre randomised controlled, double blind, placebo controlled trial.

Study population: All women planned for elective pelvic floor surgery.

Intervention: Cranberry capsules given for 6 weeks peri-operatively compared with placebo capsules.

Main study endpoints: Incidence of clinical diagnosis of UTI within 6 weeks after surgery. There is clinical diagnosis of UTI when the medical doctor (blinded for investigation arm) diagnoses and treats a UTI.

Analysis and sample size: The analysis will be performed by intention to treat. The sample size calculated is 100 women in each arm, as we expect the rate of UTI to drop from 40% to 20% with Cranberry prophylaxis, based on current incidence and results from other trials. In this sample size calculation we expect a 10% drop-out rate during the trial.

Doel van het onderzoek

Cranberry capsules given peri-operatively reduce the risk of clinical overt urinary tract infection after elective pelvic floor surgery with indwelling catheter postoperatively compared with placebo

Onderzoeksopzet

Diagnosis of urinary tract infection within six weeks after surgery.
Primary outcome is diagnosis and treatment by the medical docter based on symptoms and urine sediment.
Secondary outcome is confirmation of the diagnosis by urine culture.

Onderzoeksproduct en/of interventie

Cranberry capsules given for 6 weeks peri-operatively compared with placebo capsules.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Women planned for pelvic floor surgery, older than 18 years old, not pregnant and able to understand the Dutch language.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

Women with a history of nephrolithiasis, congenital urogenital anomaly or neurogenic bladder will be excluded. Women operated for removal of Mesh implants will also be excluded. Women using antibiotics at the moment of surgery for other medical reasons or women with chronic indwelling urinary catheter will also be excluded.

Furthermore, an allergy for cranberries is an exclusion criterion.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Dubbelblind

Controle:	Placebo

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-09-2016
Aantal proefpersonen:	200
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	11-08-2016
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	NL5840
NTR-old	NTR5995
Ander register	NL57693.101.16 : CCMO register

Resultaten