Cranberries after pelvic floor surgery for urinary tract infection prophylaxis

No registrations found.

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

Summary

ID

NL-OMON21770

Source
Nationaal Trial Register

Brief title
CUTIP trial

Health condition

urinary tract infection
cranberry
pelvic floor surgery

urineweginfectie
cranberry
bekkenbodemchirurgie

Sponsors and support

Primary sponsor: Ikazia hospital, Rotterdam (NL)
Department of Obstetrics and Gynaecology
Source(s) of monetary or material Support: fund = initiator = sponsor

Intervention

Outcome measures

Primary outcome

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.

Secondary outcome

Confirmation of the clinical diagnosis of urinary tract infection by urine culture. The type of microorganisms growing in culture of urine samples will be noted.

Study description

Background summary

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.

Study objective

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

Study design

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.

Intervention

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

Contacts

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Eligibility criteria

Inclusion criteria

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

Exclusion criteria

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.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-09-2016
Enrollment:	200

Type:	Anticipated

Ethics review

Positive opinion

Date:	11-08-2016
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	NL5840
NTR-old	NTR5995
Other	NL57693.101.16 : CCMO register

Study results