Cranberries after pelvic floor surgery for urinary tract infection prophylaxis

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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.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Urinary tract signs and symptoms
Study type	Interventional

Summary

ID

NL-OMON43215

Source
ToetsingOnline

Brief title
CUTIP trial

Condition

- Urinary tract signs and symptoms
- Obstetric and gynaecological therapeutic procedures

Synonym
cystitis, urinary tract infection

Research involving
Human

Sponsors and support

Primary sponsor: Ikazia Ziekenhuis
Source(s) of monetary or material Support: Deels door de producent van de capsules. Andere deel door een onderzoeksbudget van het Ikazia ziekenhuis en de afdeling gynaecologie.,OrthoBasics / Alfytal, Midwoud

Intervention

Keyword: cranberry, pelvic floor surgery, urinary tract infection

Outcome measures

Primary outcome

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.

Secondary outcome

Type of bacteria growing in the urine culture. An urine culture will be performed in case of clinical diagnosis or suspicion of UTI.

Study description

Background summary

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. Therefore 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.

Study 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.

Intervention

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

Study burden and risks

Cranberries are safely used worldwide as a possible prophylaxis for UTI*s and are available in many forms. Intake of the capsules is an easy intervention with low impact on daily life and might have significant beneficial effects on the recovery after pelvic floor surgery. No additional interventions will be performed in this trial.
Risks for the participants are almost negligible. Based on international literature there is only a minimal chance for a serious adverse event caused by intake of cranberry capsules.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Women undergoing pelvic floor surgery

Exclusion criteria

Allergy for cranberries is an exclusion criterium. Women with a history of nephrolithiasis, congenital urogenital anomaly or neurogenic bladder will be excluded.

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-10-2016
Enrollment:	200
Type:	Actual

Ethics review

Approved WMO

Date:	08-08-2016
Application type:	First submission

Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

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
CCMO	NL57693.101.16