

# Cranberries after pelvic floor surgery for urinary tract infection prophylaxis

No registrations found.

<b>Ethical review</b>	Positive opinion
<b>Status</b>	Pending
<b>Health condition type</b>	-
<b>Study type</b>	Interventional

## Summary

### ID

NL-OMON21770

### Source

Nationaal Trial Register

### Brief title

CUTIP trial

### Health condition

urinary tract infection  
cranberry  
pelvic floor surgery

urinewegsinfectie  
cranberry  
bekkenbodembirurgie

## 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. 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.

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 doctor 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