The effects and costs of cranberry use to prevent symptomatic urinary tract infections in nursing home residents.

Published: 07-08-2008
Last updated: 07-05-2024

To assess the effects and costs of cranberry use to prevent symptomatic UTIs in nursing home residents.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Bacterial infectious disorders
Study type	Interventional

Summary

ID

NL-OMON31677

Source
ToetsingOnline

Brief title
CRANBERRY

Condition

- Bacterial infectious disorders
- Urinary tract signs and symptoms

Synonym
Inflammation of the bladder; cystitis

Research involving
Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum
Source(s) of monetary or material Support: ZonMw doelmatigheid,Springfield Neutraceuticals BV, Oud Beijerland

Intervention

Keyword: Cranberry, Nursing home residents, Prevention, Urinary tract infection

Outcome measures

Primary outcome

•Effects study: time to first symptomatic UTI, number of symptomatic UTIs per included resident, quality of life, care dependency, compliance, side effects, medical consumption, resistance patterns of etiologic microbial agents, and costs.

•The economic evaluation will include a cost-effectiveness analysis (costs per prevented UTI) and a cost-utility analysis (costs per QALY).

Secondary outcome

N/A

Study description

Background summary

Symptomatic urinary tract infections (UTIs) are common in nursing homes residents. The point prevalence of UTIs in nursing home residents is approximately 3.8%. The incidence of UTIs varies from 44-58 per 100 residents per year. The incidence of UTIs in nursing home residents is almost similar in women and men (18-57% per year versus 19-38% per year.
Cranberry (Vaccinium macrocarpon) has been used to prevent symptomatic UTIs for several decades. Cranberries contain proanthocyanidins; stable phenolic compounds that exhibit potent anti-adhesion activity against E. coli and so preventing attachment to uroepithelial cells and colonization of the urinary tract. Recently, a double-blind placebo-controlled trial in older hospitalized patients found a reduction of 50% of symptomatic UTIs in cranberry juice users.
A recent Cochrane review showed that there are ten international studies evaluating the effect of cranberry products to prevent recurrent UTIs. There is some evidence that cranberry juice may decrease the number of symptomatic UTIs over a 12 month period, particularly for women with recurrent UTIs. It*s effectiveness for elderly men and women are less clear and needs further

investigation. Daily cranberry use could be a possible candidate for the prevention of UTIs in nursing home residents. However, despite of its shown effectiveness, a major disadvantage of cranberry use is the costs of prophylactic use. Further properly designed studies with relevant outcomes are needed.
Symptomatic UTIs are among the most common clinical infections in nursing home residents. Studying an intervention to prevent UTIs has high priority.

Study objective

To assess the effects and costs of cranberry use to prevent symptomatic UTIs in nursing home residents.

Study design

Double-blinded randomised placebo-controlled multi-centre intervention trial. Residents wil be stratified on symptomatic UTI risk (low and high risk).
The high UTI risk group includes residents with long-term catheterisation (> 1 month) and/or diabetes mellitus and/or having had at least one treated symptomatic UTI in the preceding year. In both strata, eligible residents will be randomised into an intervention group (n=500), receiving cranberry capsules or sachets and into a placebo group (n=500), receiving a placebo capsule or sachet twice a day. Residents will receive a capsule unless they can*t swallow the capsule. These residents will receive a sachet. Randomisation will take place on the level of residents.

Intervention

Two times a day one capsule of cranberry during one year.

Study burden and risks

In spite of being a natural product; there could be some side effects. It is known that a high consumption of cranberry juice might cause nausea and diarrhea. Also irritation of the stomach is possible. The placebo contains a red colorant E122 (azorubine). This colorant could cause a hypersensitivity reaction for people who are sensitive for salicylates, like asthma urticaria, angio-oedema or hyperactive behaviour.

Contacts

Public
Leids Universitair Medisch Centrum

Postbus 9600
2300 RC Leiden
NL
Scientific
Leids Universitair Medisch Centrum

Postbus 9600
2300 RC Leiden
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Age >= 65 years
Life expectancy > 1 month

Exclusion criteria

coumarine users
acute illness

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):	04-01-2008
Enrollment:	1000
Type:	Actual

Ethics review

Approved WMO

Application type:	First submission
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)

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
Other	3161 (kandidaat nummer trial register)
CCMO	NL20654.058.08