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

Gepubliceerd: 01-04-2008 Laatst bijgewerkt: 18-08-2022

N/A

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

Samenvatting

ID

NL-OMON28073

Bron
Nationaal Trial Register

Verkorte titel
CRANBERRY

Aandoening

Urinary tract infection (Urineweginfectie)

Ondersteuning

Primaire sponsor: Leiden University Medical Center (LUMC), Dept. Public Health and Primary Care.
Overige ondersteuning: ZonMw doelmatigheid;
Springfield Neutraceuticals BV

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

1. Time to first symtomatic UTI
2. number of symptomatic UITs per included resident
3. Quality of life (EQ-5D)
4. Care dependency (Care dependency scale)
5. Resistence patterns of microbial agents
6. Compliance
7. Side effects
8. Economic evaluation: cost effectivity analysis (cost per prevented UTI) and cost-utility analysis (costs per QUALY)

Toelichting onderzoek

Achtergrond van het onderzoek

Objectives/research questions.

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.

Study population and sample size.

All nursing home residents ≥ 65 years, except coumarin users, stratified by risk of symptomatic UTI (high versus low). The group with high risk of UTI includes nursing home residents with long-term catheterisation (> 1 month) and/or diabetes mellitus and/or a history of at least one treated symptomatic UTI in the preceding year.

To detect a 50% reduction in cumulative incidence of symptomatic UTIs, 1000 residents will be enrolled within a period of three months.

Eligibility Criteria.

All nursing home residents ≥ 65 years and a life expectancy > 1 month are eligible, except those using coumarin.

Study procedures.

Intervention: Cranberry capsule/sachet or placebo (both administered twice daily) during one year. The Cranberry capusule/sachet contains 1.8% proanthocyanidins (PACS)

The study does not interfere with standard care. Diagnostics and treatment will occur in accordance with current clinical guidelines.

Outcome measures.

• Effects: 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).

Analysis.

All data-analysis will be done on the basis of intention-to-treat analysis. Descriptive statistics, multivariate Cox-analyses and multivariate linear mixed models will be used.

Time schedule.

M 1-7 preparation, M 8-10 inclusion of residents, M 8-22 intervention period, M 23-36 analyses and publication.

Doel van het onderzoek

N/A

Onderzoeksopzet

At start study, after 6 and 12 months.

During UTI 3 times a week for 3 weeks.

Onderzoeksproduct en/of interventie

- Intervention (n=500): 2x dd Cranberry during 1 year.

- Controles (n=500): 2x dd Placebo during 1 year.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Age >= 65 jaar

2. Life expectancy > 1 month

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Coumarine users

2. Acute illness

Onderzoeksopzet

Opzet

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

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-08-2008
Aantal proefpersonen:	1000
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	01-04-2008
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	NL1221
NTR-old	NTR1266
Ander register	ZonMw doelmatigheid : 80-82310-98-08503
ISRCTN	ISRCTN wordt niet meer aangevraagd

Resultaten

Samenvatting resultaten
N/A