ISRCTN80031108 https://doi.org/10.1186/ISRCTN80031108

Cranberry product versus low dose trimethoprim in the prevention of recurrent urinary infections in older women: a double blind randomised trial of effectiveness and acceptability

Submission date
01/06/2006

Recruitment status
No longer recruiting

Registration date
13/06/2006

Overall study status
Completed

Last Edited
21/02/2018

Condition category
Urological and Genital Diseases

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Recent evidence shows that substances found in cranberries might help in preventing recurrent urinary infections. Recurrent urinary infections are common and troubling in older women. The usual treatment is either repeated doses of antibiotic at the time of infection or continuous low doses of antibiotic for prolonged periods of time. Unfortunately antibiotics have unwanted effects and may harm the good bacteria of your gut and lead to the development of antibiotic resistant infections.
The aim of this study is to find out whether cranberry products will reduce the occurrence of urinary infections when compared to the usual treatment with low doses of trimethoprim (an antibiotic).

Who can participate?
Adult women aged 45 years or over who have had two UTIS or episodes of cystitis in the previous 12 months

What does the study involve?
The study lasts for 6 months. At the start, participants provide a sample of urine. They are randomly allocated to one of two groups. All participants take one capsule of study medication each day, which will contain either 100mg of trimethoprim, or 500mg of cranberry extract depending on their group.
During the 6 months in the study, participants are asked to report any urine infections you have, any courses of antibiotics you take, and any side effects that you experience. At the end of the 6 months, any spare study capsules that are left will be taken back and counted.

What are the possible benefits and risks of participating?
It is possible that participants will have fewer urine infections as a result of taking one of the

study medications, but we do not know which one will prevent more infections.
There are no known side effects of cranberry product. Trimethoprim, a commonly used antibiotic, is the recommended treatment for urinary infections, but it can rarely cause side effects like upset stomach and rashes.

Where is the study run from?
Ninewells Hospital Dundee (UK)

When is the study starting and how long is it expected to run for?
September 2006 to August 2008

Who is funding the study?
Moulton Charitable Foundation (UK)

Who is the main contact?
Prof Marion McMurdo (Scientific)

Contact information

Type(s)
Scientific

Contact name
Prof Marion McMurdo

Contact details
Ageing and Health
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Additional identifiers

EudraCT/CTIS number
2006-001313-15

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
555555

Study information

Scientific Title
Cranberry or trimethoprim for the prevention of recurrent urinary tract infections? A randomized controlled trial in older women

Study objectives
1. What is the relative effectiveness of low dose trimethoprim compared to cranberry product in the prevention of urinary tract infections in older women with recurrent infections?
2. What is the acceptability of and adherence to both preventative treatments?

Ethics approval required
Old ethics approval format

Ethics approval(s)
Tayside Committee of Medical Research Ethics, 23/03/2006, ref: 06/S1402/23

Study design
Double-blind, randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Prevention

Participant information sheet

Health condition(s) or problem(s) studied
Recurrent urinary tract infections

Interventions
Trimethoprim 100 mg daily versus 500 mg cranberry product daily

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Trimethoprim

Primary outcome measure
Current primary outcome measure (as of 21/02/2018:)
First recurrence of symptomatic urinary tract infection self reported by patient during 6 month study

Previous primary outcome measure:
First recurrence of symptomatic urinary tract infection

Secondary outcome measures
Current secondary outcome measures (as of 21/02/2018):
Acceptability and adherence, measured by number of capsules left at the end of the 6 month study

Previous secondary outcome measure:
Acceptability and adherence

Overall study start date
01/09/2006

Completion date
31/08/2008

Eligibility

Key inclusion criteria
Community dwelling women aged 45 years or over with at least two antibiotic-treated urinary tract infections or episodes of cystitis in the previous 12 months

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
120

Key exclusion criteria
1. Previous urological surgery, stone or anatomical abnormalities
2. Urinary catheter
3. Diabetes mellitus
4. Immunocompromised
5. Pyelonephritis
6. Severe renal impairment
7. Blood dyscrasia
8. Symptomatic urinary tract infection (UTI) at baseline
9. Cognitive impairment precluding informed consent
10. Resident in institutional care
11. On longterm antibiotics
12. On warfarin therapy
13. Regular cranberry consumers
14. Unwilling to participate

Date of first enrolment
01/09/2006

Date of final enrolment
31/08/2008

Locations

Countries of recruitment
Scotland

United Kingdom

Study participating centre
Ageing and Health
Dundee
United Kingdom
DD1 9SY

Sponsor information

Organisation
University of Dundee (UK)

Sponsor details
Research and Innovation Services
University of Dundee
Dundee
Scotland
United Kingdom
DD1 4HN

Sponsor type
University/education

ROR
https://ror.org/03h2bxq36

Funder(s)

Funder type
Charity

Funder Name

Results and Publications

Publication and dissemination plan

Intention to publish date

Individual participant data (IPD) sharing plan
Individual participant data are not available for sharing

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/02/2009		Yes	No
Basic results		21/02/2018	21/02/2018	No	No