

A randomised double-blind study of the effect of cranberry juice in decreasing the incidence of urinary symptoms and urinary tract infections in patients undergoing pelvic radiotherapy for cancer of bladder or cervix

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| Submission date 31/08/2005 | Recruitment status No longer recruiting | <input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol |
| Registration date 16/09/2005 | Overall study status Completed | <input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results |
| Last Edited 25/09/2012 | Condition category Cancer | <input type="checkbox"/> Individual participant data |

Plain English summary of protocol
Not provided at time of registration

Study website
<http://www.crukctuglasgow.org/>

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

MI43

Study information

Scientific Title

Study objectives

To assess whether drinking cranberry juice decreases the incidence of urinary tract infections and urinary side effects

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Study design

Randomised double blind placebo controlled parallel group trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Prevention

Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied

Bladder or cervix cancer

Interventions

Cranberry juice or placebo

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Cranberry juice or placebo

Primary outcome measure

Increase in Common Toxicity Criteria (CTC) grade of urinary tract symptoms OR development of urinary tract infection

Secondary outcome measures

Other CTC toxicities

Overall study start date

24/02/2003

Completion date

01/01/2008

Eligibility

Key inclusion criteria

1. Patients with cervical cancer about to start standard chemoradiation (weekly cisplatin chemotherapy plus radiation therapy as below) or radiation therapy (4300-4500 cGy over 20 fractions +/-selectron radiotherapy)
2. OR patients with bladder cancer about to commence standard radical radiotherapy (5000-5240 cGy over 20 fractions).
3. Age ≥ 18 years.
4. ECOG performance status ≤ 2 .
5. Written informed consent and the ability to comply with the requirements of the study.

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

250

Key exclusion criteria

1. Pregnant or lactating women are excluded. Female patients of child-bearing potential are eligible provided they have a negative urine pregnancy test prior to enrolment and agree to use approved contraceptive precautions during the trial and for 6 months afterwards.

2. Patients with irritable bowel syndrome (they may experience episodes of diarrhoea as a side effect of drinking cranberry juice).
3. Patients who are diabetic (due to the high sugar content of the juice).
4. Patients who have rheumatoid arthritis (the acidic juices may exacerbate joint pain).
5. Patients with urinary symptoms or urinary tract infections at baseline.
6. Patients receiving antispasmodics or antibiotics for urinary symptoms.
7. Patients with an indwelling urinary catheter.

Date of first enrolment

24/02/2003

Date of final enrolment

01/01/2008

Locations

Countries of recruitment

Scotland

United Kingdom

Study participating centre

North Glasgow University Hospitals NHS Trust

Glasgow

United Kingdom

G11 6NT

Sponsor information

Organisation

Greater Glasgow NHS Board, North Glasgow Division (UK)

Sponsor details

West Research Office

Administration Building

Western Infirmary

Glasgow

Scotland

United Kingdom

G11 6NT

Sponsor type

Hospital/treatment centre

Website

<http://www.ngt.org.uk/research/home.htm>

ROR

<https://ror.org/05kdz4d87>

Funder(s)

Funder type

Charity

Funder Name

Western Endowment Fund (UK)

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---------------------------------|---------|--------------|------------|----------------|-----------------|
| Results article | results | 01/03/2012 | | Yes | No |