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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

Submission date 31/08/2005	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 16/09/2005	**Overall study status** Completed	
Last Edited 25/09/2012	**Condition category** Cancer	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
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

Study type(s)
Prevention

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

Key secondary outcome(s))
Other CTC toxicities

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

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

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
United Kingdom

Scotland

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)

ROR
https://ror.org/05kdz4d87

Funder(s)

Funder type
Charity

Funder Name
Western Endowment Fund (UK)

Results and Publications

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
Study website	Study website	11/11/2025	11/11/2025	No	Yes