

Assessment of the palatability of elemental nutritional supplements compared to non-elemental supplements in people with pelvic cancers and people without cancer, and whether this changes following treatment with radiotherapy

Submission date 20/09/2005	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 21/11/2005	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
Last Edited 10/09/2012	Condition category Cancer	<input type="checkbox"/> Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Jervoise Andreyev

Contact details
Faculty of Medicine
Imperial College
Chelsea & Westminster Hospital
369 Fulham Road
London
United Kingdom
SW10 9NH

Additional identifiers

Protocol serial number
CCR2376

Study information

Scientific Title

Study objectives

To assess in adults with pelvic cancers and in adults without cancer:

1. The inter- and intra observer variation in acceptability of a range of nutritional supplements
2. Whether patients experience a change in taste during a course of radical radiotherapy
3. Whether there is a difference in taste between adults with pelvic malignancies and healthy controls

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Study design

Randomised controlled trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Pelvic (gynaecological, urological or rectal) cancers

Interventions

Subjects were randomised to one of five groups. Each group was assigned a target quantity of 3 different elemental sip feeds (Group 1, 20%, Group 2, 50%, Group 3, 75% of calorie requirements taken as E028 extra liquid; Group 4, 50% of calorie requirements taken as E028 extra powder; Group 5, 50% of calorie requirements taken as Emsogen powder).

Intervention Type

Supplement

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Elemental nutritional supplements

Primary outcome(s)

Taste assessed by visual analogue scale

Key secondary outcome(s))

Not provided at time of registration

Completion date

31/03/2006

Eligibility

Key inclusion criteria

Patients about to embark on a course of radical pelvic radiotherapy for pelvic malignancy

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Key exclusion criteria

1. Unwilling or unable to give informed consent to participate in the study
2. A clinical condition precluding oral feeding (e.g. dysphagia, bowel obstruction)
3. Unable to tolerate milk
4. Controls with a previous history of pelvic malignancy or currently receiving chemotherapy or radiotherapy

Date of first enrolment

26/01/2004

Date of final enrolment

31/03/2006

Locations

Countries of recruitment

United Kingdom

England

Study participating centre

Faculty of Medicine

London

United Kingdom

SW10 9NH

Sponsor information

Organisation

Imperial College London (UK)

ROR

<https://ror.org/041kmwe10>

Funder(s)

Funder type

Industry

Funder Name

SHS International

Funder Name

Dr Andreyev's Personal Research Fund

Funder Name

Royal Marsden NHS Foundation Trust (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	01/02/2006		Yes	No