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	Recruitment status No longer recruiting	Prospectively registered		
20/09/2005		☐ Protocol		
Registration date	Overall study status	Statistical analysis plan		
21/11/2005	Completed	[X] Results		
Last Edited	Condition category	Individual participant data		
10/09/2012	Cancer			

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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SW10 9NH

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

Secondary study design

Randomised controlled trial

Study setting(s)

Not specified

Study type(s)

Treatment

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

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 measure

Taste assessed by visual analogue scale

Secondary outcome measures

Not provided at time of registration

Overall study start date

26/01/2004

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

Age group

Adult

Sex

Both

Target number of participants

50

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

England

United Kingdom

Study participating centre Faculty of Medicine

London United Kingdom SW10 9NH

Sponsor information

Organisation

Imperial College London (UK)

Sponsor details

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

Sponsor type

University/education

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

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	01/02/2006		Yes	No