ISRCTN35391431 https://doi.org/10.1186/ISRCTN35391431

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	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 21/11/2005	**Overall study status** Completed	
Last Edited 10/09/2012	**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

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
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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