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ENIGMA - modified fat - A randomised controlled trial using a modified fat diet in patients undergoing pelvic radiotherapy

Submission date 29/09/2006	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 29/09/2006	**Overall study status** Completed	
Last Edited 16/08/2012	**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
N0258171429

Study information

Scientific Title

Study objectives
Can a low fat diet (made up of 'normal' or 'long chain' fats) or a low fat diet containing additional 'medium chain' fats prevent or reduce bowel side effects in people undergoing a course of pelvic radiotherapy.

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)
Hospital

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
Cancer: Pelvic radiotherapy

Interventions
Randomised test intervention vs no intervention controls, non-blinded (Phase III)

Intervention Type
Other

Phase
Phase III

Primary outcome measure

1. Bowel toxicity (assessed using IBD-Q) at week 4
2. Small bowel damage (citrulline/faecal calprotectin) at week 2 and week 4

Secondary outcome measures
Not provided at time of registration

Overall study start date
03/01/2006

Completion date
01/05/2007

Eligibility

Key inclusion criteria
1. Patients who are about to undergo a course of radical or adjuvant pelvic radiotherapy for gynaecological, urological or lower gastrointestinal malignancy
2. Patients able to give informed consent to participate
3. Patients with healthy liver function

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
105

Key exclusion criteria
1. Patients unable or unwilling to give informed consent
2. Patients who have already started radiotherapy
3. Patients who have a condition precluding sage oral nutrition
4. Patients with compromised liver function
5. Urology patients participating in the IMRT clinical trial.

Date of first enrolment
03/01/2006

Date of final enrolment
01/05/2007

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Gastrointestinal Unit
London
United Kingdom
SW3 6JJ

Sponsor information

Organisation
Record Provided by the NHSTCT Register - 2006 Update - Department of Health

Sponsor details
The Department of Health, Richmond House, 79 Whitehall
London
United Kingdom
SW1A 2NL
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dhmail@doh.gsi.org.uk

Sponsor type
Government

Website
http://www.dh.gov.uk/Home/fs/en

Funder(s)

Funder type
Government

Funder Name
The Royal Marsden NHS Foundation Trust (UK) - NHS R&D Support Funding

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	01/06/2012		Yes	No