

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	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 29/09/2006	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 16/08/2012	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

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Additional identifiers

Protocol serial number
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

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s)

Not provided at time of registration

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

Healthy volunteers allowed

No

Age group

Adult

Sex

All

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 safe 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**

United Kingdom

England

Study participating centre**Gastrointestinal Unit**

London

United Kingdom

SW3 6JJ

Sponsor information**Organisation**

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

Funder(s)

Funder type

Government

Funder Name

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

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	01/06/2012		Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes