

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

<b>Submission date</b> 29/09/2006	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 29/09/2006	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 16/08/2012	<b>Condition category</b> 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**  
Gastrointestinal Unit  
Department of Medicine  
Royal Marsden NHS Trust  
Fulham Road  
London  
United Kingdom  
SW3 6JJ

## 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 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**

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

+44 (0)20 7307 2622

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?
<a href="#">Results article</a>	results	01/06/2012		Yes	No