

# Elemental Nutrition in Gastrointestinal symptom management during pelvic radiotherapy (enigma)

<b>Submission date</b> 30/09/2005	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 30/09/2005	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 10/09/2012	<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

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## Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N0258152650

# Study information

## Scientific Title

## Acronym

ENiGMa

## Study objectives

To identify in patients having pelvic radiotherapy if elemental diet given for 3 weeks can reduce bowel symptoms and change other indicators of these symptoms.

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

Not provided at time of registration

## Study design

Randomised open label controlled parallel group trial

## Primary study design

Interventional

## Secondary study design

Randomised controlled trial

## Study setting(s)

Hospital

## Study type(s)

Not Specified

## 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 cancers

## Interventions

Randomised test intervention versus no intervention controls, non-blinded Phase III

## Intervention Type

Other

## Phase

Phase III

**Primary outcome measure**

To assess bowel toxicity using IBDQ and to assess whether there are differences in the score in patients in their intervention arm and the control.

**Secondary outcome measures**

Not provided at time of registration

**Overall study start date**

25/11/2004

**Completion date**

31/07/2006

## Eligibility

**Key inclusion criteria**

102 RMH patients, with a diagnosis of gynaecological or urological malignancy. Will be undergoing a course of radical or adjuvant pelvic radiotherapy to a curative dose (including patients undergoing concomitant chemotherapy).

**Participant type(s)**

Patient

**Age group**

Not Specified

**Sex**

Not Specified

**Target number of participants**

102

**Key exclusion criteria**

1. Patients with condition precluding oral nutrition
2. Patients undergoing conformal radiotherapy or intra-cavity brachytherapy
3. Patients with clotting disorders

**Date of first enrolment**

25/11/2004

**Date of final enrolment**

31/07/2006

## Locations

**Countries of recruitment**

England

United Kingdom

**Study participating centre**  
**Medicine Section**  
Sutton, Surrey  
United Kingdom  
SM2 5PT

## Sponsor information

**Organisation**  
Department of Health

**Sponsor details**  
Richmond House  
79 Whitehall  
London  
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**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)

**Funder Name**  
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	01/06/2008		Yes	No