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

Submission date 30/09/2005	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 30/09/2005	**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

Contact name
Dr Jervoise Andreyev

Contact details
Medicine Section
Royal Marsden NHS Trust
Downs Road
Sutton, Surrey
United Kingdom
SM2 5PT
+44 (0)20 8643 8901

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 readiotherapy 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
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)

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?
Results article	results	01/06/2008		Yes	No