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EDMONd - Elemental diet in bowel obstruction

Submission date	Recruitment status	[X] Prospectively registered
06/02/2017	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
20/02/2017	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
13/08/2021	Cancer	

Plain English summary of protocol
https://www.cancerresearchuk.org/about-cancer/find-a-clinical-trial/a-study-of-a-new-diet-for-women-with-a-blockage-in-the-bowel-edmond

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Public

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number
NCT03150992

Secondary identifying numbers
32895

Study information

Scientific Title
EDMONd – A feasibility study of Elemental Diet as an alternative to parenteral nutrition for patients with inoperable Malignant bowel Obstruction

Acronym
EDMONd

Study objectives
The aim of the study is to provide 'proof of concept' of Elemental Diet (ED) as an acceptable /useful feeding option for patients with inoperable bowel obstruction (IBO) and to examine the impact of ED on quality of life.

Ethics approval required
Old ethics approval format

Ethics approval(s)
South East Coast – Surrey Research Ethics Committee, 20/12/2016, ref: 16/LO/2079

Study design
Non-randomised; Interventional; Design type: Treatment, Dietary

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet
See additional files

Health condition(s) or problem(s) studied
Specialty: Cancer, Primary sub-specialty: Gynaecological Cancers; UKCRC code/ Disease: Cancer/ Malignant neoplasms of female genital organs

Interventions
All participants receive the Elemental Diet (ED). The ED will be provided in the form of Elemental 028 Extra Liquid. Patients will be assessed by a clinician and specialist oncology dietician and given an individual plan of ED introduction. ED requires phased introduction to achieve tolerance of the course of 3-5 days, under the supervision of the study dietician. Following introduction of ED, patients will be discharged from the hospital (as per normal clinic practise) and followed up for 2 weeks. They will have a telephone follow up assessment once a week for two weeks. All other assessments will follow the standard of care. During the follow up assessment, patients will be assessed using the Memorial Symptom Assessment Scale and asked to complete a nutritional diary and Quality of Life questionnaires.

Intervention Type
Other

Primary outcome measure
1. Taste acceptability of ED is measured on 1-5 grading in nutritional diary once per week for two weeks
2. Incidence of vomiting is measured on MSAS scale at day 1 of ED induction, discharge and once per week for two weeks
3. Incidence of pain is measured on MSAS scale at day 1 of ED induction, discharge and once per week for two weeks

Secondary outcome measures
1. The number (proportion) of patient who can tolerate ED following presentation with IBO and can subsequently be treated with palliative chemotherapy is measured by reviewing hospital case notes at patient completion of study
2. The number of patients alive at the end of the study is measured by reviewing hospital case notes at patient completion of study
3. Health Related Quality of Life is measured on EORTC-QLQ-C30 at day 1 of ED induction, discharge and once per week for two weeks
4. Nutritional Intake is measured by the number of ED cartons taken in 24 hours
5. Incidence of vomiting is measured on MSAS scale at day 1 of ED induction, discharge and once per week for two weeks

Overall study start date
01/12/2015

Completion date
31/12/2019

Eligibility

Key inclusion criteria
1. Age 18 years and over
2. Confirmed inoperable bowel obstruction due to disseminated malignancy
3. Ability to tolerate 500 ml of liquid
4. Capacity to give informed consent

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 34; UK Sample Size: 34

Key exclusion criteria
1. Bowel obstruction that can be managed with surgical intervention
2. Complete bowel obstruction and inability to tolerate small amount of liquid

Date of first enrolment
01/03/2017

Date of final enrolment
28/02/2019

Locations

Countries of recruitment
England

United Kingdom

Study participating centre

Royal Surrey County Hospital
Egerton Road
Guildford
United Kingdom
GU2 7XX

Study participating centre
Royal Sussex County Hospital
Eastern Road
Brighton
United Kingdom
BN2 5BE

Study participating centre
Guy's Hospital
Great Maze Pond
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SE1 9RT

Sponsor information

Organisation
Royal Surrey County Hospital NHS Foundation Trust

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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/050bd8661

Funder(s)

Funder type
Charity

Funder Name
Target Ovarian Cancer

Alternative Name(s)

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Planned publication in a peer reviewed scientific journal, conference presentation and publication online.

Intention to publish date
28/10/2021

Individual participant data (IPD) sharing plan
The current data sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version V2	04/01/2017	20/02/2017	No	Yes
Poster results	results presented in poster at the European Society for Gynaecological Oncology in (ESGO)	14/12/2020	13/08/2021	No	No
HRA research summary			28/06/2023	No	No