ISRCTN16535341 https://doi.org/10.1186/ISRCTN16535341

Investigating the effectiveness of a nutritional intervention to enhance patient recovery after elective major lung surgery

Submission date 28/11/2016	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 19/12/2016	**Overall study status** Completed	
Last Edited 10/10/2024	**Condition category** Cancer	

Plain English summary of protocol
https://www.cancerresearchuk.org/about-cancer/find-a-clinical-trial/a-study-looking-at-carbohydrate-drinks-after-lung-surgery-to-improve-recovery-thirsty

Contact information

Type(s)
Public

Contact name
Mrs Amy Kerr

Contact details
-
-
United Kingdom
-
-
amy.kerr@heartofengland.nhs.uk

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
CPMS 31591

Study information

Scientific Title
Adults undergoing major lung surgery randomised to nutritional intervention or equivalent volume in water to assess the effects on post-operative outcomes

Acronym
ThIRStY

Study objectives
The aim of this study is to assess the feasibility of carrying out a randomised controlled trial comparing the effectiveness of a nutritional intervention (NI) of preoperative carbohydrate-loading drinks and early postoperative nutritional supplement drinks compared to receiving an equivalent volume of water in enhancing recovery after major lung surgery (MLS)

Ethics approval required
Old ethics approval format

Ethics approval(s)
Wales REC 7, 05/09/2016, ref: 16/WA/0254

Study design
Randomized; Both; Design type: Prevention, Dietary, Management of Care, Qualitative

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied
Specialty: Cancer, Primary sub-specialty: Lung Cancer; UKCRC code/ Disease: Cancer/ Malignant neoplasms of respiratory and intrathoracic organs

Interventions
After written informed consent, the patient will be randomised, before surgery, to either a nutritional intervention or water. Participants will be individually randomised into the study in an

equal 1:1 ratio. Randomisation will be by a web based randomisation system. Patients will be stratified by diagnosis (cancer or benign) and type of surgery (key hole or open).

The nutritional intervention in brief the evening before surgery 4x200mls, the morning of surgery, 2X200mls of carbohydrate-loading supplement will be given. In the postoperative period patients will be given 125ml polymeric nutritional supplement drink twice a day from the period immediately after their operation for 2 weeks. The control group will consume the same quantity of water thus any benefit from the intervention will not be due to preventing dehydration.

Follow up will be 3 months post-surgery with Visual Analogue Score (VAS), Quality of Recovery and EQ5D questionnaires.

Intervention Type
Other

Primary outcome measure
Recruitment rate is recorded as the number of eligible participant who consent to participate in the study by 12 months.

Secondary outcome measures
1. Reasons for failure to recruit are assessed by screening log at the end of the study
2. Ease and efficiency of randomisation process is assessed by speed in which patients can be randomised and whether important prognostic data can be collected pre-operatively at the end of the study
3. Compliance rate of the intervention and contamination rate of the control group is assessed by data gathered by questionnaire and interview, we would expect to have a compliance of 50% of prescribed carbohydrate drinks and ONS taken as scheduled by the end of recruitment
4. Robustness of data collection processes during patient's hospital stay is assessed by completeness of important peri-operative data to be over 90% for each patient.
5. Follow-up rate of patients at 3 months is assessed by a response rate of 80% at 3 months
6. Reasons for loss of follow-up (if any) are measured at 3 months,100% of mortality data will be captured.
7. Questionnaire best reflects patient experience is assessed by patient interviews at 3-4 week post-surgery.
8. Variability and distribution of quality of life questionnaires measured by return rate up to 3 months after surgery

Overall study start date
16/06/2016

Completion date
21/12/2017

Eligibility

Key inclusion criteria
1. Patients aged over 18 years
2. Undergoing elective major lung surgery (MLS)
3. Able to consume nutritional drinks prior to surgery
4. Able to give written informed consent

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 60; UK Sample Size: 60

Total final enrolment
64

Key exclusion criteria
1. Likely inability to comply with completion of the study questionnaires
2. Body mass index (BMI) < 18.5 kg/m2
3. Receiving enteral nutrition
4. Known pregnancy

Date of first enrolment
22/09/2016

Date of final enrolment
21/09/2017

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Heartlands Hospital
Bordsley green
Birmingham
United Kingdom
B9 5SS

Sponsor information

Organisation
Heart of England NHS Foundation Trust

Sponsor details
Birmingham Heartlands Hospital
Bordesley Green East
Birmingham
England
United Kingdom
B9 5ST
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Sponsor type
Hospital/treatment centre

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Heart of England NHS Foundation Trust

Results and Publications

Publication and dissemination plan
This feasibility study is designed to identify if a substantive trial is possible. Although a definitive answer to the key research question on effectiveness of nutritional intervention in patient undergoing major thoracic surgery cannot be provided, the findings of this feasibility study will be of scientific interest to others in their own right. The dissemination strategy has been planned in three aspects. The first will ensure that patients and health professionals are informed of the feasibility findings; the second will engage multi-disciplinary professionals to support a proposal of a definitive RCT and the third will be to submit a grant application dependant on the success of the feasibility study (2018).

Intention to publish date
31/12/2018

Individual participant data (IPD) sharing plan
The datasets generated and/or analysed during the current study during this study will be included in the subsequent results publication.

IPD sharing plan summary

Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Preprint results	non-peer-reviewed results	13/09/2021	21/09/2021	No	No
Results article		28/06/2022	30/06/2022	Yes	No
HRA research summary			28/06/2023	No	No
Plain English results			10/10/2024	No	Yes