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

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

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Contact details

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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) $< 18.5 \text{ kg/m}^2$
- 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