

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	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 19/12/2016	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 10/10/2024	Condition category Cancer	<input type="checkbox"/> Individual participant data

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

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Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

ClinicalTrials.gov (NCT)

Nil known

Protocol serial number

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

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

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**

United Kingdom

England

Study participating centre**Heartlands Hospital**

Bordsley green

Birmingham

United Kingdom

B9 5SS

Sponsor information**Organisation**

Heart of England NHS Foundation Trust

Funder(s)**Funder type**

Hospital/treatment centre

Funder Name

Heart of England NHS Foundation Trust

Results and Publications

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?
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
Preprint results	non-peer-reviewed results	13/09/2021	21/09/2021	No	No