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

Central Portfolio Management System (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