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A trial of a very low calorie diet prior to cholecystectomy operation in obese patients

Submission date
10/03/2015

Recruitment status
No longer recruiting

Registration date
26/03/2015

Overall study status
Completed

Last Edited
09/05/2016

Condition category
Nutritional, Metabolic, Endocrine

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
The procedure used to remove a gallbladder is called laparoscopic cholecystectomy. This study is investigating whether following a very low calorie diet for 2 weeks prior to a laparoscopic cholecystectomy operation reduces operation time and makes the operation easier. We will also investigate if post-operative complications are reduced as a result of following this diet. The very low calorie diet is used routinely to improve weight loss surgery. The diet causes the liver to shrink and this shrinkage allows the operation to be performed much easier. As the gallbladder is attached to the liver we want to see if this diet can also make a cholecystectomy operation easier.

Who can participate?
Adult patients with a BMI of over 30 who are awaiting a cholecystectomy operation

What does the study involve?
Participants are randomly allocated to one of two groups: very low calorie diet group or normal diet group. The surgeon will not know which group they are in. We will look at how long the operation takes between the two groups. We will also look at the difference between the two groups in weight loss, complication rate after surgery, length of stay after surgery, day case rates and how difficult the operation was from a technical point of view.

What are the possible benefits and risks of participating?
By taking part in this trial participants will be contributing to the advancement of medical knowledge of what is 'best practice' for the laparoscopic cholecystectomy procedure. If they are allocated to the low calorie arm they will lose some weight in the short term. Previous research has shown that weight loss reduces the size of the liver, which makes it easier for the surgeon to move the liver out of the way in order to remove the gallbladder. This should make the operation time shorter, and will, we hope, reduce the incidence of complications post-operatively. Previous studies have used low calorie diets for operations to the stomach which have helped to reduce the liver size and make the operation easier. The risks associated with this study are those associated with the operation. The procedure will not be different to the procedure normally carried out for the removal of gallbladders. Disadvantages of this study are that if participants do fall into the group for the low calorie diet, this will mean a lifestyle

adjustment for that period. Previous studies have shown that some people may feel light headed or dizzy on this diet especially when standing from a sitting or lying position. Additionally, some people following low calorie diets have felt more tired and some have had more headaches than usual. Participants will be asked to inform the research nurse of any side effects that they have and information on how to do this will be given on the diet sheet.

Where is the study run from?
Norfolk and Norwich University Hospital (UK)

When is the study starting and how long is it expected to run for?
September 2010 to May 2015

Who is funding the study?
Norfolk and Norwich University Hospital (UK)

Who is the main contact?
Mr Michael Lewis
michael.lewis@nnuh.nhs.uk

Contact information

Type(s)
Public

Contact name
Mr Michael Lewis

Contact details
Dept of Surgery
Norfolk and Norwich University Hospital
Colney Lane
Norwich
United Kingdom
NR4 7UY
+44 (0)1603 287583
michael.lewis@nnuh.nhs.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
A randomised, single blinded trial, assessing the effect of a two week preoperative very low calorie diet (VLCD) on laparoscopic cholecystectomy procedure in obese patients

Acronym
DOLCE

Study objectives
The aim of this study is to examine the effect of a two week VLCD on laparoscopic cholecystectomy in obese patients. We hypothesize that the reduction in size of the liver will improve surgical access and dissection, reduce operation complexity and ultimately operating time. By reducing operative difficulty, we propose that there will be a reduction in procedure related complications and an increase in the number of day case laparoscopic cholecystectomies.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Cambridge South, 11/02/2100, ref: 10/H0305/78

Study design
Interventional single-centre prospective randomised trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

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

Health condition(s) or problem(s) studied
Obese patients undergoing elective cholecystectomy surgery

Interventions
Intervention group: two week pre-operative very low calorie diet
Control group: continue normal diet

Intervention Type
Procedure/Surgery

Primary outcome measure

Duration of surgery

Secondary outcome measures
1. Pre-operative weight loss
2. Post operative complication rate
3. Post operative length of stay
4. Post operative day case rate
5. Perceived difficulty of the operation

Overall study start date
01/09/2010

Completion date
01/05/2015

Eligibility

Key inclusion criteria
1. Adult patients with capacity to consent
2. Body mass index (BMI) over 30kg/m2
3. Symptomatic gallstone disease placed on a waiting list for elective laparoscopic cholecystectomy operation

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
46

Key exclusion criteria
1. Presence of any pre-existing liver disease
2. Diabetes mellitus
3. Confirmed common bile duct stones
4. Previous abdominal surgery

Date of first enrolment
01/05/2011

Date of final enrolment
01/05/2013

Locations

Countries of recruitment

England

United Kingdom

Study participating centre
Norfolk and Norwich University Hospital
Colney Lane
Norwich
United Kingdom
NR4 7UY

Sponsor information

Organisation
Norfolk and Norwich University Hospital (UK)

Sponsor details
Colney Lane
Norwich
England
United Kingdom
NR4 7UY

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/021zm6p18

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Norfolk and Norwich University Hospital (UK)

Results and Publications

Publication and dissemination plan

We plan to submit the results of the trial at the end of april to the BJS

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/05/2016		Yes	No