

A prospective cohort study of laparoscopic sleeve gastrectomy for weight loss in obese patients on haemodialysis: proof of concept

Submission date

21/06/2011

Recruitment status

No longer recruiting

☐ Prospectively registered

☐ Protocol

Registration date

21/06/2011

Overall study status

Completed

☐ Statistical analysis plan

☒ Results

Last Edited

18/12/2015

Condition category

Urological and Genital Diseases

☐ Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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London

United Kingdom

SE5 9RS

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

10025

Study information

Scientific Title

A prospective cohort study of laparoscopic sleeve gastrectomy for weight loss in obese patients on haemodialysis: proof of concept

Study objectives

Obesity can cause chronic kidney disease and lead to kidney failure. However, obese patients are less likely to be eligible for kidney transplantation - the best treatment option for patients with kidney failure. Weight loss surgery is an effective treatment for weight loss but has not yet been studied systematically in patients with kidney failure.

This research aims to find out whether weight loss surgery is an effective and safe treatment for obesity in patients with kidney failure on haemodialysis.

Ethics approval required

Old ethics approval format

Ethics approval(s)

10/H0716/55

Study design

Non-randomised, interventional, treatment

Primary study design

Interventional

Secondary study design

Non randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

Health condition(s) or problem(s) studied

Renal and Urogenital

Interventions

1. 15 volunteer haemodialysis patients with a body mass index > 35 will have keyhole surgery to reduce the size of their stomach to limit food intake and hunger.
2. The weight loss surgery procedure selected is the sleeve gastrectomy
3. In this operation, the size of the stomach is permanently reduced to one-third of its original size by removing some of the stomach to form a smaller, tube shaped stomach.
4. Another 15 patients with a body mass index >35 who choose not to have keyhole surgery will also be studied as a comparison group
5. Weight loss, achieving the body mass index criteria for listing for kidney transplantation,

quality of life, changes in blood pressure and blood fats and the safety of the operation will be measured over 1 year

Intervention Type

Drug

Phase

Not Applicable

Drug/device/biological/vaccine name(s)

Orlistat

Primary outcome measure

1. BMI <35 kg/m²
2. Measured at timepoint(s) of 6 and 12 months

Secondary outcome measures

No secondary outcome measures

Overall study start date

07/02/2011

Completion date

30/09/2011

Eligibility**Key inclusion criteria**

1. On haemodialysis for at least 90 days
2. Male or female, aged > 18 years
3. BMI > 35 kg/m²
4. Previously attempted weight loss (surgery arm only)
5. Fit for anesthesia and surgery (surgery arm only)
6. Written informed consent

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

Planned Sample Size: 30; UK Sample Size: 30

Key exclusion criteria

1. Pregnancy
2. History of chronic liver disease
3. Previous bariatric surgery, gastric surgery or large hiatus hernia
4. Psychiatric illness, including anxiety, mood and untreated eating disorders
5. Malnutrition (assessed by subjective global assessment)
6. Infection or course of antibiotics within the last month
7. Peritoneal dialysis

Date of first enrolment

07/02/2011

Date of final enrolment

30/09/2011

Locations**Countries of recruitment**

England

United Kingdom

Study participating centre

Denmark Hill

London

United Kingdom

SE5 9RS

Sponsor information**Organisation**

Kings College London

Sponsor details

Strand

London

England

United Kingdom

WC2R 2LS

Sponsor type

University/education

Website

<http://www.kcl.ac.uk/index.aspx>

ROR

<https://ror.org/0220mzb33>

Funder(s)

Funder type

Charity

Funder Name

British Renal Society

Alternative Name(s)

BRS

Funding Body Type

Private sector organisation

Funding Body Subtype

Associations and societies (private and public)

Location

United Kingdom

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/01/2012		Yes	No