

Outcomes of bariatric surgery in patients with liver cirrhosis

Submission date 17/05/2017	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 26/05/2017	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 12/03/2019	Condition category Digestive System	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

Cirrhosis occurs when the liver becomes scarred due to long-term damage. It can stop the liver from working properly, causing liver failure. A main risk factor for liver cirrhosis is from being obese or overweight. When people are obese, they sometimes undergo a weight loss surgery called bariatric surgery. This is a major operation that either removes a part of stomach or puts a band over it so that patients feel full. It can help reduce the chances of liver cirrhosis, among many other obesity related conditions. The aim of this study is to analyse the effects of obesity surgery in patients with liver cirrhosis to see if patients with liver cirrhosis that undergo the surgery have different complication rates, if they surgery is effective with weight loss and if it helps improve liver function.

Who can participate?

Adults aged 18 to 70 with obesity and liver cirrhosis who had bariatric surgery

What does the study involve?

Participants who have undergone a bariatric surgery are included in this study and have their medical records reviewed. Data is reviewed before and their surgery to see if they had any complications, to review their weight and height, compare blood analyses, and to see if their liver function has improved.

What are the possible benefits and risks of participating?

There are no direct benefits or risks with participating.

Where is the study run from?

This study is taking place in 19 hospitals in Spain

When is the study starting and how long is it expected to run for?

January 2017 to March 2018

Who is funding the study?

Organisation Spanish Society of Endocrinology and Nutrition (SEEN) (Spain)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
IIBSP-BAR-2016-108

Study information

Scientific Title
BARiatric surgery in patients with liver CIRRhOsis

Acronym
CIRROBAR

Study objectives
The aim of this study is to assess short and long-term evolution and complications of patients with liver cirrhosis and obesity that are submitted to obesity surgery in Spain.

Ethics approval required
Old ethics approval format

Ethics approval(s)

Ethics Committee of the Research Institute of Hospital de la Santa Creu i Sant Pau – IIB Sant Pau, 01/03/2017, ref: IIBSP-BAR-2016-108

Study design

Observational multi-centre retrospective case series

Primary study design

Observational

Secondary study design

Case series

Study setting(s)

Hospital

Study type(s)

Other

Participant information sheet

Not available in web format, please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied

Obesity

Interventions

This is a retrospective study. Participants are included for this study if they already have had a bariatric surgery and have been followed up since the surgery date until the inclusion data in the study by their endocrinology team.

Eligible participants have clinical and analytical data collected from their baseline visit prior to surgery. Then, participants undergo the surgery and then have their routine follow up visits. The number of follow up visits differs from one patient to another according to their date of surgery. Data is collected yearly from when the surgery occurred until the present. The data collected from participants include age, date of surgery, type of surgery, weight, height and BMI, presence of diabetes, cause of cirrhosis, hepatic biopsa, blood tests, and any complications they may have.

Intervention Type

Procedure/Surgery

Primary outcome measure

Short and long term evolution of patients with liver cirrhosis submitted to obesity surgery is measured using patient records at 1 month and one year after bariatric surgery and for long term evolution, at the last visit in each patient

Secondary outcome measures

1. Causes of cirrhosis, staging (Child, MELD) and degree of hepatic insufficiency (albumin, platelets, INR, liver function tests) are measured using patient records at the last pre-surgical visit

2. Hepatic pathology after bariatric surgery (staging (Child, MELD), degree of liver failure (albumin, platelets, INR, liver function tests), liver biopsies, hepatic decompensations postIQ (encephalopathy, ascites, Bleeding), development of hepatocarcinoma)) are measured using patient records at the patients last follow up visit
3. Frequency of early complications are measured using patient records at early postoperative (<30 days post surgery) or late (> 30 days post surgery)
4. Obesity comorbidities (diabetes, hypertension, dyslipidemia, SAHS) are measured using patient records at the last pre-surgical visit and at each year after surgery until study inclusion
5. Body weight is measured using patient records at the last pre-surgical visit and at each year after surgery until study inclusion

Overall study start date

01/01/2017

Completion date

01/03/2018

Eligibility

Key inclusion criteria

1. Patient with obesity and liver cirrhosis submitted to bariatric surgery in Spain
2. Aged 18 to 70 years old

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

Minimum of 30 patients

Key exclusion criteria

Not applicable

Date of first enrolment

01/06/2017

Date of final enrolment

01/12/2017

Locations

Countries of recruitment

Spain

Study participating centre

Hospital de la Santa Creu i Sant Pau

Carrer de Sant Quintí

89

Barcelona

Spain

08026

Study participating centre

Hospital del Mar

Passeig Marítim

25-29

Barcelona

Spain

08003

Study participating centre

Hospital Arnau de Vilanova

Av. Alcalde Rovira Roure

80

Lleida

Spain

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Study participating centre

Hospital Universitario Reina Sofía.

Av. Menéndez Pidal, s/n

14004

Córdoba

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Study participating centre

Hospital Vall d'Hebron

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Study participating centre
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Study participating centre
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Study participating centre
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Study participating centre
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Study participating centre
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Study participating centre
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Sponsor information

Organisation

Organisation Spanish Society of Endocrinology and Nutrition (SEEN)

Sponsor details

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Sponsor type

Research organisation

Website

www.seen.es

ROR

<https://ror.org/01tk4y529>

Funder(s)

Funder type

Research organisation

Funder Name

Organisation Spanish Society of Endocrinology and Nutrition (SEEN)

Results and Publications

Publication and dissemination plan

Planned publication in a high-impact peer reviewed journal

Intention to publish date

01/03/2019

Individual participant data (IPD) sharing plan

The current data sharing plans for the current study are unknown and will be made available at a later date

IPD sharing plan summary

Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/02/2019	12/03/2019	Yes	No

