ISRCTN15009106 https://doi.org/10.1186/ISRCTN15009106

Outcomes of bariatric surgery in patients with liver cirrhosis

Submission date 17/05/2017	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol
Registration date 26/05/2017	**Overall study status** Completed	[_] Statistical analysis plan [X] Results
Last Edited 12/03/2019	**Condition category** Digestive System	[_] 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?
Dr Inka Miñambres
iminambres@santpau.cat

Contact information

Type(s)
Scientific

Contact name
Dr Inka Miñambres

Contact details
Endocrinology Services
Hospital de la Santa Creu i Sant Pau
C/ Mas Casanovas 90
Barcelona
Spain
08026
+34 (0)93 55 65 661
iminambres@santpau.cat

Additional identifiers

Protocol serial number
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

Primary study design
Observational

Study design
Observational multi-centre retrospective case series

Study type(s)
Other

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(s)
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

Key secondary outcome(s)
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

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

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

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
25198

Study participating centre
Hospital Universitario Reina Sofía.
Av. Menéndez Pidal, s/n
14004
Córdoba
Spain
14004

Study participating centre
Hospital Vall d'Hebron
Passeig de la Vall d'Hebron
119-129
Barcelona
Spain
08035

Study participating centre
Hospital Universitari Parc Taulí
Parc Taulí, 1
Sabadell
Barcelona
Spain
08208

Study participating centre
Hospital Universitario A Coruña
As Xubias, 84
15006 A Coruña
La Coruña
Spain
15006

Study participating centre
Hospital Virgen de la Victoria
Campus de Teatinos
S/N
Málaga
Spain
29010

Study participating centre
Hospital Universitario Gregorio Marañón
Calle del Dr. Esquerdo
46
Madrid
Spain
28007

Study participating centre
Clínica Universidad de Navarra.
Av. de Pío XII
36
31008
Navarra
Pamplona
Spain
31008

Study participating centre
Hospital Clínic i Universitari
Carrer de Villarroel
170
Barcelona
Spain
08036

Study participating centre
Complejo Asistencial Universitario de León
Calle Altos de nava
s/n
León
Spain
24001

Study participating centre
Hospital Valle del Nalón Asturias
33920
Polígono de Riaño
1
Langreo
Spain
33920

Study participating centre
Complexo Hospitalario Universitario de Vigo, Pontevedra
Estrada de Clara Campoamor
341
Vigo Pontevedra
Vigo
Spain
36312

Study participating centre
Hospital Clínico San Carlos
Calle del Prof Martín Lagos
s/n
Madrid
Spain
28040

Study participating centre
Hospital Universitario de Bellvitge
Carrer de la Feixa Llarga
s/n
L'Hospitalet de Llobregat
Barcelona
Spain
08907

Study participating centre
Hosp. Univ. Virgen del Rocio de Sevilla
Av. Manuel Siurot
Sevilla
Spain
41013

Study participating centre
Hospital Regional Universitario de Málaga
Av. de Carlos Haya
s/n
Málaga
Spain
29010

Study participating centre
Hospital Universitari Germans Trias i Pujol
Carretera de Canyet, S/N,
08916 Badalona
Barcelona
Spain
08916

Sponsor information

Organisation
Organisation Spanish Society of Endocrinology and Nutrition (SEEN)

ROR
https://ror.org/01tk4y529

Funder(s)

Funder type
Research organisation

Funder Name
Organisation Spanish Society of Endocrinology and Nutrition (SEEN)

Results and Publications

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