# Outcomes of bariatric surgery in patients with liver cirrhosis

Submission date	Recruitment status No longer recruiting	[X] Prospectively registered		
17/05/2017		☐ Protocol		
Registration date	Overall study status Completed	Statistical analysis plan		
26/05/2017		[X] Results		
<b>Last Edited</b> 12/03/2019	<b>Condition category</b> Digestive System	[] Individual participant data		
12/03/2013	Digestive System			

#### 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

#### Clinical Trials Information System (CTIS)

Nil known

#### ClinicalTrials.gov (NCT)

Nil known

#### 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

#### Study design

Observational multi-centre retrospective case series

#### Primary study design

Observational

#### 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

# **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

#### 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
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes