

A randomized phase IV clinical trial comparing Nadolol and Isosorbide Mononitrate (ISMN) with the combination of Endoscopic Banding Ligation plus Nadolol and ISMN in the prevention of variceal rebleeding

Submission date 28/12/2005	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 24/03/2006	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 25/10/2022	Condition category Circulatory System	<input type="checkbox"/> Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Prof Jaime Bosch

Contact details
Liver Unit
Hospital Clinic
Villarroel 170
Barcelona
Spain
08036
+34 (0)932275790
jbosch@clinic.ub.es

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

LEB-VE2002

Study information

Scientific Title

A randomized phase IV clinical trial comparing Nadolol and Isosorbide Mononitrate (ISMN) with the combination of Endoscopic Banding Ligation plus Nadolol and ISMN in the prevention of variceal rebleeding

Study objectives

The combination of endoscopic banding ligation with drug therapy improves the results of drug therapy alone in the prevention of rebleeding in patients with cirrhosis who have suffered an acute variceal bleeding. The assumptions for the sample size were that the control group would have a 32% incidence of rebleeding at one-year, and that this would be reduced to 15% in the experimental group. Since this is a one sided hypothesis, we calculated that with an alpha of 5% and a beta of 20%, at least 160 patients would be required to detect such a difference.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Date of approval by the ethics committee: 23/Sep/2002. Number: 02-0294.

Study design

Randomized controlled multicenter open study

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Not specified

Study type(s)

Prevention

Participant information sheet

Health condition(s) or problem(s) studied

Variceal bleeding

Interventions

Control group: nadolol + isosorbide mononitrate for the prevention of rebleeding

Experimental group: nadolol + isosorbide mononitrate + endoscopic banding ligation for the prevention of rebleeding.

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

Rebleeding from any source

Secondary outcome measures

1. Rebleeding from esophageal varices
2. Rebleeding from other portal hypertensive sources
3. Death
4. Death from variceal bleeding
5. Death from rebleeding
6. Frequency of severe adverse events
7. Relation between changes in hepatic venous pressure gradient and clinical events
8. Development of any complication of portal hypertension or death
9. Changes in variceal size
10. Transfusion requirements
11. Requirement for alternative therapies
12. Costs

Overall study start date

01/02/2003

Completion date

01/02/2005

Eligibility**Key inclusion criteria**

1. Age between 18-75
2. Diagnosis of cirrhosis
3. Hematemesis or melena within 7 days prior to inclusion
4. Esophageal or gastroesophageal varices as the source of bleeding
5. Written informed consent
6. Exclusion of pregnancy in woman of child-bearing potential

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Upper age limit

75 Years

Sex

Both

Target number of participants

160 patients

Key exclusion criteria

1. Hepatocellular carcinoma >5 cm or multinodular
2. Creatinine >2 mg/dl
3. Child-Pugh \leq 13 points
4. Contraindications to beta-adrenergic blockers
5. Contraindications to ISMN
6. Banding ligation in the 3 months before the present episode of variceal bleeding
7. Previous portosystemic derivative therapy
8. Bleeding from fundal or ectopic varices
9. Total portal vein thrombosis or portal vein cavernomatosis
10. The patient was already on beta-adrenergic blockers and ISMN for the prevention of variceal bleeding

Date of first enrolment

01/02/2003

Date of final enrolment

01/02/2005

Locations

Countries of recruitment

Spain

Study participating centre

Liver Unit

Barcelona

Spain

08036

Sponsor information

Organisation

Individual Sponsor (Spain)

Sponsor details

Dr Jaime Bosch
Hepatic Hemodynamic Laboratory
Hospital Clinic
Villarroel 170
Barcelona
Spain
08036
+34 (0)932275790
jbosch@clinic.ub.es

Sponsor type

Not defined

Funder(s)

Funder type

Government

Funder Name

Health Investigation Fund (Fondo de Investigación Sanitaria), Ministry of Health, PI020739.

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

Not provided at time of registration

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	pub	01/08/2009		Yes	No