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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	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 24/03/2006	**Overall study status** Completed	
Last Edited 25/10/2022	**Condition category** Circulatory System	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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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 ≤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
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Sponsor information

Organisation
Individual Sponsor (Spain)

Sponsor details

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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