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Endoscopic sclerotherapy compared with no specific treatment for the primary prevention of bleeding from oesophageal varices: a randomised controlled multicentre trial

Submission date
06/08/2003

Recruitment status
No longer recruiting

Registration date
13/08/2003

Overall study status
Completed

Last Edited
18/07/2008

Condition category
Digestive System

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

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
90/006

Study information

Scientific Title

Study objectives
To compare endoscopic sclerotherapy (ES) with no specific treatment for the primary prevention of bleeding from oesophageal varices in patients with cirrhosis.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Liver cirrhosis

Interventions
Prophylactic sclerotherapy versus no specific treatment.

For more information, please contact the College voor Zorgverzekeringen (Health Care Insurance Board) on infoSBA@cvz.nl.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Not provided at time of registration

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/05/1986

Completion date
31/05/1993

Eligibility

Key inclusion criteria
1. Adults with endoscopically documented grade II, III or IV oesophageal varices
2. Absence of prior bleeding from varices
3. Evidence of active and/or progressive liver disease (e.g. as indicated by repeatedly elevated serum transaminases or increasing serum bilirubin levels or development of ascites within the past year)
4. Documented increase in the size of oesophageal varices
5. All patients gave informed consent

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
166

Key exclusion criteria
1. Use of beta-blockers and nitrates
2. Malignancy
3. Haemophilia
4. Age older than 70 - 75 years
5. No opportunity for follow-up visits

Date of first enrolment
01/05/1986

Date of final enrolment
31/05/1993

Locations

Countries of recruitment
Netherlands

Study participating centre
Erasmus MC
Rotterdam
Netherlands
2040 CA

Sponsor information

Organisation
Dutch Health Care Insurance Board (College voor Zorgverzekeringen) (The Netherlands)

Sponsor details
PO Box 320
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Sponsor type
Government

Funder(s)

Funder type
Government

Funder Name
Dutch Health Care Insurance Board (College Voor Zorgverzekeringen) (The Netherlands) (ref: OG 90/006)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

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	Results	15/08/2003		Yes	No