

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	<input type="checkbox"/> Prospectively registered
Registration date 13/08/2003	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 18/07/2008	Condition category Digestive System	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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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