

Brief intervention in patients with esophageal varices (abnormal, enlarged veins in the tube that connects the throat and stomach)

Submission date 26/03/2021	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 24/04/2021	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 04/05/2021	Condition category Digestive System	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

Esophageal varices are abnormal, enlarged veins in the tube that connects the throat and stomach (esophagus). This condition occurs most often in people with serious liver diseases. Esophageal varices develop when normal blood flow to the liver is blocked by a clot or scar tissue in the liver.

The aim of the present study is to examine how motivational interviewing to reduce any alcohol use affects mortality among patients with esophageal varices caused by chronic liver diseases.

Who can participate?

All patients over the age of 18 with any chronic liver disease with esophageal varices.

What does the study involve?

Patients are interviewed using the Alcohol Use Disorders Identification Test and Addiction Severity Index before randomization to motivational interviewing (n=49) and no intervention (n=50). All participants are followed every third month for 2 years with structured interviews regarding their alcohol use. Primary outcome are mortality.

What are the possible benefits and risks of participating?

None

Where is the study run from?

Capio StGöran Hospital, Medical Department, Stockholm, Sweden

When is the study starting and how long is it expected to run for?

December 2012 to December 2019

Who is funding the study?

Region Stockholm, Sweden

Who is the main contact?
Knut Stokkeland, M.D., Ph.D.,

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Nil known

Study information

Scientific Title
Effects of a brief intervention on mortality in patients with liver cirrhosis complicated by esophageal varices – a randomized controlled trial

Study objectives
The aim of this study is to investigate whether MI directed against alcohol use reduces mortality among patients with any severe chronic liver disease, both alcohol-related and non-alcohol related. As a secondary aim, the impact of the intervention on alcohol consumption during follow-up is evaluated.

Ethics approval required
Old ethics approval format

Ethics approval(s)

Approved 09/04/2013, Swedish Ethical Review Authority (Etikprövningsmyndigheten, Box 2110, 750 02, Uppsala, Sweden; +46 10-475 08 00; registrator@etikprovning.se), ref: 2013/187-31)

Study design

Randomized controlled trial with two parallel groups

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

See additional file (in Swedish)

Health condition(s) or problem(s) studied

Alcohol use among patients with liver cirrhosis

Interventions

Brief intervention (a psychological counselling technique based on motivational interviewing)

Following written informed consent and screening, included patients are subject to computerized randomization into two groups: one group receiving alcohol intervention and one control group receiving no intervention. The randomization are operated externally by the Karolinska Trial Alliance. The study is monitored according to good clinical practice by Karolinska Trial Alliance.

The intervention group receives a single 45 minutes appointment using the MI technique, focusing on reducing the patient's alcohol consumption. MI is a direct, client-centered counselling to elicit behavioral changes by helping clients to explore and resolve ambivalence. The technique builds on a non-judgmental stance; reflective listening; developing discrepancy; rolling with resistance, avoiding argument; and supporting efficacy to change.

All patients are followed by time-line follow back telephone interviews by a study nurse every third month for two years and patients report alcohol consumption per day the last three months as detailed as possible. Alcohol consumption after intervention is explored as change in alcohol consumption between baseline and follow-up. Consumption is defined in terms of standard drinks containing 14 grams of alcohol. Binge drinking before inclusion is defined as any answer other than 0 on question E5 in the ASI. Binge drinking during follow up is defined as alcohol consumption equal to or more than five standard drinks per day, based on data from the TLFB interviews. The total amount of alcohol consumed and the amount of alcohol drunk per week during follow up are calculated based on TLFB data.

Patients are interviewed using the Alcohol Use Disorders Identification Test and Addiction Severity Index before randomization to motivational interviewing or no intervention. All participants are followed every third month for 2 years with structured interviews regarding their alcohol use.

Intervention Type

Behavioural

Primary outcome measure

Overall mortality rate is measured from the medical files which are based on the National Public Death Rate. The study is censored at the time of death or at the end of the study period. Death is registered even if the patients have dropped out of the study.

Secondary outcome measures

1. Alcohol use measured using ASI, AUDIT at inclusion and TLFB on follow-up
2. Alcohol consumption after the intervention is explored as change in alcohol consumption between baseline and follow-up. Consumption are defined in terms of standard drinks containing 14 grams of alcohol

Overall study start date

06/12/2012

Completion date

31/12/2019

Eligibility

Key inclusion criteria

All patients over the age of 18 with any chronic liver disease with esophageal varices diagnosed by endoscopy or computer tomography at Capho S:t Görans Hospital, Stockholm

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

84

Total final enrolment

99

Key exclusion criteria

Hepatic encephalopathy too severe for interviewing

Date of first enrolment

09/04/2013

Date of final enrolment

31/12/2019

Locations**Countries of recruitment**

Sweden

Study participating centre

Capio S:t Görans Hospital

Sankt Göransplan 1

Stockholm

Sweden

11229

Sponsor information**Organisation**

Capio S:t Göran Hospital

Sponsor details

S:t Görans plan 1

Stockholm

Sweden

11219

+46 (0)858703608

charlotte.soderman@capiostgoran.se

Sponsor type

Hospital/treatment centre

Website

<http://ki.se/en/startpage>

Funder(s)**Funder type**

Government

Funder Name

Region Stockholm, Sweden

Results and Publications

Publication and dissemination plan

Planned publication in a peer-reviewed journal.

Intention to publish date

30/06/2021

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are available on reasonable request from Charlotte Söderman, M.D., Ph.D., Medical Department, Capho StGöran Hospital, StGörans plan 1, 112 19 Stockholm, Sweden, charlotte.soderman@capiostgoran.se

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet			04/05/2021	No	Yes
Protocol file	version v2	17/08/2015	04/05/2021	No	No