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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	[_] Prospectively registered [X] Protocol
Registration date 24/04/2021	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 04/05/2021	**Condition category** Digestive System	[_] Individual participant data [_] 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

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
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

Study type(s)
Treatment

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(s)
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.

Key secondary outcome(s))
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

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 Capio S:t Görans Hospital, Stockholm

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

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

Funder(s)

Funder type
Government

Funder Name
Region Stockholm, Sweden

Results and Publications

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, Capio 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
Participant information sheet	Participant information sheet version v2	11/11/2025	11/11/2025	No	Yes
Protocol file		17/08/2015	04/05/2021	No	No