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Patient-centred nurse-led clinic for patients with liver cirrhosis

Submission date
31/01/2023

Recruitment status
No longer recruiting

Registration date
10/02/2023

Overall study status
Completed

Last Edited
13/04/2026

Condition category
Digestive System

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

Plain English summary of protocol
Background and study aims
Cirrhosis is scarring of the liver caused by continuous, long-term liver damage. The rate of death from liver cirrhosis is high. The risk of death depends on how the complications are treated and prevented. The only treatment for advanced liver cirrhosis is liver transplantation. To be eligible for transplantation, the patient will have to meet a number of criteria. Furthermore, there needs to be an organ available for the patient. Organs for transplant are limited. Consequently, only a minority of patients with advanced liver cirrhosis are transplanted. Focus is therefore to minimize, avoid or remove factors that can lead to complications. Initiatives to do so could include lifestyle changes, increased self-care and increased adherence. Subgroups of patients with liver cirrhosis have low levels of health literacy and may therefore need patient-tailored information and guidance. One-third of episodes with complications are found to be preventable with closer follow-up in an outpatient setting. The aim of this study is to establish a nurse-led clinic for patients with liver cirrhosis in order to reduce acute admissions.

Who can participate?
The study will include adult patients with decompensated liver cirrhosis followed at Aarhus University Hospital, Denmark. Decompensated liver cirrhosis is characterised by one or more of the following complications: ascites, variceal bleeding or hepatic encephalopathy. Eligible patients will need close contact with the hospital in order to prevent acute admissions.

What does the study involve?
The intervention will be individual contact with liver-nurses in the clinic. The contact will be individual and can include telephone contacts, physical appointments and/or communication with relatives or caregivers. Patients will only be followed until they have a good understanding of their condition, are well-regulated on medical treatment, and have a high level of self-care.

A cohort of approximately 800 patients that have the diagnosis of liver cirrhosis will be the main data source in the study. The study will run for 2-3 years (2022-2025). Key parameters for acute admission will continuously be monitored prior to, during and after the study. The effect will be calculated using acute admission data from all patients in the period mentioned above.

What are the possible benefits and risks of participating?
Participants will hopefully achieve better understanding of their disease, symptoms and ways to self-care. Furthermore, the participants will have a closer personal contact to the hospital and acute admissions will be reduced. The potential risk of participating is close to zero.

Where is the study run from?
The study will run from Aarhus University Hospital, Denmark.

When is the study starting and how long is it expected to run for?
August 2019 to September 2024

Who is funding the study?
The study is funded by donations from Central Denmark Region, Aarhus University Hospital and The Novo Nordisk Foundation.

Who is the main contact?
Senior researcher, associated professor Palle Bager, pallbage@rm.dk

Contact information

Type(s)
Principal investigator

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Additional identifiers

Protocol serial number
NNF20OC0066034

Study information

Scientific Title
Patient-centred nurse-led clinic for patients with liver cirrhosis, aiming to improve the clinical course of the condition. A quasi-experimental longitudinal study with a dynamic cohort

Study objectives
After full implementation of a patient-centered nurse-led clinic, the number of clinical incidences, leading to admission to hospital- ward or outpatient clinic, will drop by 25% for the whole cohort.

Ethics approval required
Ethics approval not required

Ethics approval(s)
The study does not require ethical approval in Denmark. The study does not include medical intervention and no human biological material will be collected.

Primary study design
Interventional

Study design
Single-centre quasi-experimental longitudinal study including a dynamic cohort

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Preventing acute admissions for patients with decompensated liver cirrhosis

Interventions
The key intervention will be to establish a patient-centred nurse-led clinic.
The clinic will offer patients individual talks about their disease and the related problems. Using the tool motivational interviewing, the nurse will identify the most important issues for each patient. Based on the shared decision-making, customized and comprehensive care plans for each patient will be developed. Furthermore, the nurses will have delegated authorisation to adjust selected medical treatment.
As the aim is to prevent acute admission to hospital. Consequently, the intervention will be individual, - in content, in frequency, and in duration.
Eligible patients will be recruited from the hospital ward or the outpatient clinic.
The patients will be screened for possible health-related problems (e.g. ascites, nutrition, compliance, medical treatment, alcohol abuse) and possible accompanying problems (e.g. housing, weak social network, transport, economic).
Based on screening, an individual intervention will be planned and executed. This could include physical appointment, education of the patient (and relatives), telephone calls, contact to the primary health care etc.
The intervention will end (and the patient will stop in the trial) when the patient is well informed and well established with the condition of liver cirrhosis and able to perform self-care. The intervention will also end if the patient turns out to be non-compliant or obviously not able to benefit from the intervention; - or if the patient dies.
Data on patient contact and the nature of intervention will continuously be collected.
Furthermore, the overall hospital-related activity for the total cohort of patients with liver cirrhosis (approximately 800 patients) will be monitored on a monthly basis (interrupted time series) aiming (at the end of the trial) to be able to describe the effect of the intervention as changes in acute activity.

Intervention Type

Behavioural

Primary outcome(s)
Acute admissions to hospital- ward or outpatient clinic by 25% for the whole cohort at the end of trial compared to data prior to the intervention.
Data on acute admissions and specific procedures linked to the admission have continuously been recorded is a hospital database since 2019. The primary measurement will be data from this source in order to detect changes (on cohort level) after the implementation of the clinic. The individual patient will add data to this database, regardless of participation in the trial or not. The total cohort will be regarded as dynamic, as some patients will leave the cohort (die or move) and new patients will enter the cohort. Calculation will be performed on the whole cohort (approximately 800 patients) and per 100 patients.

Key secondary outcome(s)
1. Every trial activity for the patients included will be recorded at each trial activity. This includes type of activity and content. These data combined with data described under primary outcome measures, will be used for health economic analysis (budget impact analysis) at the end of trial.
2. Feasibility of establishing a nurse-led clinic will be measured by qualitative methods.

Completion date
30/09/2024

Eligibility

Key inclusion criteria
1. Eligible patients will be adult patients with decompensated liver cirrhosis who are estimated to be able to benefit from the intervention.
2. Patients who need information, coordination and close contact with the hospital in order to prevent acute admissions.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 Years

Upper age limit
130 Years

Sex
All

Total final enrolment
55

Key exclusion criteria
1. Patients who are well informed and/or have a well-functioning network.
2. Patients who are predominantly non-compliant and/or not receptive to information and care.

Date of first enrolment
01/01/2022

Date of final enrolment
30/06/2024

Locations

Countries of recruitment
Denmark

Study participating centre
Aarhus University Hospital
Department of Hepatology and Gastroenterology
Palle Juul-Jensens Boulevard 99
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Sponsor information

Organisation
Aarhus University Hospital

ROR
https://ror.org/040r8fr65

Funder(s)

Funder type
Government

Funder Name
Region Midtjylland

Alternative Name(s)
Central Denmark Region, RM

Funding Body Type
Government organisation

Funding Body Subtype
Local government

Location
Denmark

Funder Name
Aarhus Universitetshospital

Alternative Name(s)
Aarhus University Hospital, AUH

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
Denmark

Funder Name
Novo Nordisk Pharma

Alternative Name(s)
Novo Nordisk Japan, Novo Nordisk Pharma Ltd

Funding Body Type
Private sector organisation

Funding Body Subtype
For-profit companies (industry)

Location
Japan

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		01/04/2026	13/04/2026	Yes	No