

# Long term abdominal drains in end stage cirrhosis

<b>Submission date</b> 07/10/2015	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 07/10/2015	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 04/03/2021	<b>Condition category</b> Digestive System	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

Cirrhosis is a serious complication of liver disease, which involves widespread scarring of the liver. The damage to the liver caused by cirrhosis means that eventually the liver is unable to fulfil its normal functions, ultimately leading to liver failure. Cirrhosis develops gradually, however the damage to the liver is irreversible, and gets worse over time. When cirrhosis is so advanced that the liver is unable to function, a liver transplant is the only treatment option. If a person with advanced cirrhosis does not meet the requirements for a liver transplant, then they are unlikely to survive for longer than six months. One of the most common complications of advanced cirrhosis is a build-up of fluid in the abdomen (ascites). Ascites can be very uncomfortable and make it difficult to breathe and eat properly. The only way to relieve these symptoms is by having the excess fluid drained through a small cut in the abdomen. Despite this, the fluid immediately starts to build-up again, and so patients have to attend hospital every one-two weeks to have the draining procedure repeated. Draining fluid in this way can be very expensive, as well as causing pain and infection. In some advanced cancers, ascites are managed by having a more permanent drain placed into the abdomen (long-term abdominal drain). This means that smaller amounts of fluid can be drained more often in the patients' own home. Repeated hospital admission can cause distress and so being able to manage aspects of their treatment at home may be an attractive prospect for advanced cirrhosis patients. The aim of this study is to look into the possibility of using long-term abdominal drains for treating ascites in advanced cirrhosis patients.

### Who can participate?

Adults with advanced cirrhosis who have untreatable ascites.

### What does the study involve?

Patients are randomly allocated into two groups. Those in the first group receive standard care, which involves repeated drainage in hospital. Those in the second group have a long-term abdominal drain implanted, so that the fluid build-up can be drained several times a week. This takes place in the patients' own homes and the process is supported by community nurses. Health and wellbeing of the patients in both groups are monitored for a period of three months. The impact of the different care methods on the patients' families and carers is also assessed.

What are the possible benefits and risks of participating?

Not provided at time of registration

Where is the study run from?

Brighton & Sussex Clinical Trials Unit

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

October 2015 to November 2018

Who is funding the study?

National Institute for Health Research (UK)

Who is the main contact?

Ms Jean Timeyin

## Contact information

### Type(s)

Scientific

### Contact name

Mrs Jean Timeyin

### Contact details

Brighton & Sussex Clinical Trials Unit

16 Bloomsbury Street

Brighton & Sussex University Hospitals

Brighton

United Kingdom

BN2 1HQ

## Additional identifiers

### Protocol serial number

19235

## Study information

### Scientific Title

Palliative long-term abdominal drains versus repeated drainage in individuals with untreatable ascites due to advanced cirrhosis: a feasibility randomised controlled trial

### Study objectives

The aim of this study is to investigate the acceptability and feasibility in using long term abdominal drains to treat patients with cirrhosis.

### Ethics approval required

Old ethics approval format

### Ethics approval(s)

## **Study design**

Randomised; Interventional and Observational; Design type: Treatment, Qualitative

## **Primary study design**

Interventional

## **Study type(s)**

Treatment

## **Health condition(s) or problem(s) studied**

Topic: Gastroenterology; Subtopic: Gastroenterology; Disease: All Gastroenterology

## **Interventions**

Patients will be randomly allocated to one of two groups:

Group 1: Patients receive current standard care only (hospital based abdominal drainage)

Group 2: Patients have a drain implanted into the abdominal area so that fluid can be drained at home.

Community (district) nurses (and, if identified as required, specialist community palliative care teams) will support the patients. Patients will be monitored over three months to assess symptoms and quality of life and the impact on family/carers. Likely costs to the NHS of the new technique will be calculated.

## **Intervention Type**

Procedure/Surgery

## **Primary outcome(s)**

Acceptability of LTAD to patients/carers and staff to be measured at end of study (3 months) or at the time of patient death, whichever occurs first.

## **Key secondary outcome(s)**

There are no secondary outcome measures.

## **Completion date**

16/11/2018

# **Eligibility**

## **Key inclusion criteria**

1. Aged 18 years or over
2. Presence of untreatable (refractory) ascites, defined as:
  - 2.1. Ascites that are unresponsive to fluid and sodium restriction and high dose diuretic treatment (spironolactone 400 mg and/or furosemide 160 mg) and/or intolerance of diuretics
  - 2.2. Recurs rapidly after LVP (need for one or more LVP per month).
3. Child Pugh Score of greater than 9. unless specifically decided by the medical team that they are to receive only palliative treatment. If less than 9, the participant is considered palliative by medical team.

4. 4. Registered with a GP in Brighton and Hove or West Sussex with community Integrated Primary Care Team provision from Sussex Community NHS Trust
5. Ability to speak read and understand English
6. Capacity to give informed consent as defined using the Capacity to Consent Checklist
7. Signed, informed consent prior to any study specific procedures

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

18 years

**Sex**

All

**Total final enrolment**

59

**Key exclusion criteria**

1. Either loculated or chylous ascites
2. Presence of > grade 1 hepatic encephalopathy (specified by West Haven Criteria – appendix 13)
3. Evidence of active infection that in the investigator's opinion would preclude insertion of LTAD (for example, bacterial peritonitis) – such patients would need to receive appropriate treatment and could then be reconsidered
4. A candidate for liver transplantation
5. Psychosocial issues which in the opinion of the medical team will preclude study participation

**Date of first enrolment**

01/10/2015

**Date of final enrolment**

15/06/2018

**Locations****Countries of recruitment**

United Kingdom

England

**Study participating centre**

**Brighton & Sussex Clinical Trials Unit**  
16 Bloomsbury Street  
Brighton  
United Kingdom  
BN2 1HQ

## Sponsor information

**Organisation**  
Brighton and Sussex University Hospitals NHS Trust

## Funder(s)

**Funder type**  
Government

**Funder Name**  
National Institute for Health Research

**Alternative Name(s)**  
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

**Funding Body Type**  
Government organisation

**Funding Body Subtype**  
National government

**Location**  
United Kingdom

## Results and Publications

**Individual participant data (IPD) sharing plan**  
The datasets generated during and/or analysed during the current study are/will be available upon reasonable request from the chief investigator (trial.monitors@bsuh.nhs.uk)

**IPD sharing plan summary**  
Available on request

**Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>	embedded qualitative study results	19/12/2020	04/03/2021	Yes	No
<a href="#">Results article</a>	results	01/07/2020	04/03/2021	Yes	No
<a href="#">Protocol article</a>	protocol	27/07/2018		Yes	No
<a href="#">HRA research summary</a>			28/06/2023	No	No
<a href="#">Participant information sheet</a>	Participant information sheet	11/11/2025	11/11/2025	No	Yes