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Long term abdominal drains in end stage cirrhosis

Submission date	Recruitment status	[_] Prospectively registered
07/10/2015	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
07/10/2015	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
04/03/2021	Digestive System	

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
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BN2 1HQ

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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)
South Central - Hampshire A Research Ethics Committee,17/06/2015, ref: 15/SC/0257

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

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

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

Secondary outcome measures
There are no secondary outcome measures.

Overall study start date
01/10/2015

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 48; UK Sample Size: 48

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
England

United Kingdom

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

Sponsor details
Village Way
Falmer
Brighton
England
United Kingdom
BN1 9PH

Sponsor type
Hospital/treatment centre

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

Publication and dissemination plan
Planned publication in a high-impact peer reviewed journal.

Intention to publish date
06/09/2019

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?
Protocol article	protocol	27/07/2018		Yes	No
Results article	embedded qualitative study results	19/12/2020	04/03/2021	Yes	No
Results article	results	01/07/2020	04/03/2021	Yes	No
HRA research summary			28/06/2023	No	No