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Home versus hospital drainage of fluid from the abdomen (ascites) for patients with advanced cirrhosis

Submission date
28/07/2022

Recruitment status
Recruiting

Registration date
15/08/2022

Overall study status
Ongoing

Last Edited
09/06/2025

Condition category
Digestive System

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims

The liver can be damaged (scarred) by excessive alcohol and viral infections. If liver damage continues, this scarring leads to permanent damage (cirrhosis). As cirrhosis progresses, it causes a painful buildup of fluid (ascites) in the belly (abdomen). Initially, drugs can treat ascites, but these may stop working, leading to untreatable ascites. A liver transplant is then the best option. Most people, however, do not receive a transplant due to concerns about their alcohol use or lack of donors.

People with cirrhosis and untreatable ascites who do not receive a liver transplant live on average for about six months. Medical care then focuses on controlling symptoms and having the best possible quality of life. This is known as palliative care. Current standard palliative care for untreatable ascites involves coming into the hospital for 1-2 days, putting a thin tube into the abdomen for a few hours and draining 5-15 L of fluid. This reduces the pain from ascites. However, as the ascites build up quickly, hospital visits are needed every 10-14 days. Our patients describe repeated hospital drainage as ”devastating” and “unbearably painful”.

For people with untreatable ascites due to cancer (rather than cirrhosis), palliative care involves placing another tube, a long-term abdominal drain (LTAD), into their abdomen. This tube is fitted in the hospital but stays in place for months. Nurses/caregivers then drain smaller amounts of fluid (1-2 L) up to three times a week in the community. LTADs avoid frequent hospital visits and can improve their quality of life.

LTADs are not routinely offered to people with cirrhosis as they can have complicated social issues like addiction, making community care difficult. Secondly, people with cirrhosis are at increased risk of ascitic fluid infection. The concern is that LTADs might further increase this risk. It remains uncertain, therefore, if LTADs could improve the quality of life for people with cirrhosis.

We ran a small study (2015-18) with 36 patients with cirrhosis and untreatable ascites. Half received LTADs and half continued with standard hospital drainage. LTAD insertion went well with no major complications. Almost all with LTAD were managed in the community with lower overall costs compared with hospital drainage. Participants were willing to fill in study

questionnaires and take part in interviews. Patients and clinical staff told us that LTADs were acceptable to them.

We are now running a larger study to understand the risks/benefits of palliative LTADs in people with cirrhosis. Our aim is to see if palliative LTADs result in a better quality of life in patients with fluid in the abdomen due to liver scarring, compared with the current standard of care.

Who can participate?
Patients with advanced cirrhosis and untreatable ascites if a liver transplant is not an option

What does the study involve?
In this study, people who agree to take part will have ascites drained through either LTAD or repeated hospital visits. Community nurses will visit LTAD patients at home up to three times a week for ascites drainage. Researchers will visit ALL participants at home every 2 weeks for 12 weeks for safety monitoring and also record the quality of life, symptoms, carer workload and use of NHS services (using questionnaires). We will record all infections that occur. We will talk with patients/caregivers/clinical staff to ask for their views about the research. The most important measure chosen to see if LTAD is a good option for people with cirrhosis is quality of life. The study has been designed with help of the patients/caregivers who are part of the research team.

What are the possible benefits and risks of participating?
There may be no direct benefits to patients. Information collected about patients taking part in this study will help us determine whether home drains are a suitable option for people with cirrhosis and if so, whether they improve quality of life. The complications observed in the LTAD group are similar to that seen in the hospital drain group, except leakage and inflammation around the drain site were higher in the home drain group (about 40 in 100 people versus about 11 in 100 people). Draining ascites to dryness in the hospital after insertion of LTAD can reduce leakage and this is now our standard practice.

Where is the study run from?
University Hospitals Sussex NHS Foundation Trust (UK)

When is the study starting and how long is it expected to run for?
May 2022 to September 2026

Who is funding the study?
National Institute for Health and Care Research (NIHR)

Who is the main contact?
Prof Sumita Verma (Chief Investigator) (UK)

Study website
https://www.bsms.ac.uk/research/clinical-and-experimental-medicine/brighton-and-sussex-ctu/current-studies/reduce2.aspx

Contact information

Type(s)
Principal Investigator

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Type(s)
Public

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
314073

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
CPMS 52988, IRAS 314073

Study information

Scientific Title
Palliative long-term abdominal drains versus repeated drainage in untreatable ascites due to advanced cirrhosis: A randomised controlled trial (REDUCe 2 study)

Acronym
REDUCe 2

Study objectives
Palliative long-term abdominal drains, by moving care to the community, will result in a better quality of life compared with hospital drainage in patients with refractory ascites due to advanced cirrhosis

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 29/06/2022, South Central - Oxford C Research Ethics Committee Health Research Authority (Ground Floor, Temple Quay House, 2 The Square, Bristol, BS1 6PN, United Kingdom; +44(0)207 1048241; oxford.rec@hra.nhs.uk), ref: 22/SC/0164

Study design
Randomized interventional multi-centre non-blinded parallel-group

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Community, Hospital

Study type(s)
Treatment, Safety, Efficacy

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

Health condition(s) or problem(s) studied
Complications of cirrhosis

Interventions
Current interventions as of 01/11/2023:
Study design
This RCT will follow on from the REDUCe feasibility study and will compare the insertion of a palliative tunnelled long-term abdominal drain (LTAD) (Group 1 intervention) to the standard of care (large volume paracentesis (LVP) (Group 2) in the management of refractory ascites due to advanced cirrhosis. This multi-centre, non-blinded parallel-group RCT with up to 3 months of follow-up will be conducted across 35 sites in England, Scotland and Wales. We aim to recruit

310 patients. 30 patients, 20 informal caregivers and 20 healthcare professionals will also be invited to give their perceptions/perspectives of LTAD and LVP using qualitative methods.

The study will commence recruitment in October/November 2022 and is due to be completed in September 2026 which is the last patient last visit (LPLV). We have built in a 6-month lead-up time to secure HRA approvals and ensure all sites are set up and appropriate training provided. After the LPLV we have time to ensure the dataset is clean and locked for the statisticians to undertake the analysis. These timelines have been reviewed and approved by the funder: NIHR HTA. Participants will be approached by a member of the clinical team and provided with information about the study. The sample size has been calculated using HRQoL as the primary endpoint and the study will be conducted in a large number of sites in England and Scotland to ensure the sample size will be recruited in a timely manner. If they decide to proceed with the study they will be invited to the hospital for a screening visit. At this visit, consent will be received and blood will be taken for routine analysis and a sample of ascitic fluid will be taken to ensure there is no underlying infection. If there is this will be treated with oral antibiotics prior to any drain insertion. If the participant is eligible and they are willing to continue they will be randomised to either the Intervention (the LTAD) or standard of care (LVP). The participant will receive a phone call prior to the baseline visit so that the treatment group can be discussed with them and they know what to expect at that visit. At the baseline visit, safety blood will be taken as well as vital signs. At this visit, the questionnaires are completed. There are between three to four questionnaires to be completed by the participant at each visit with a total of 6 visits after the baseline visit.

If the participant is randomised to the LTAD arm they will be followed up at home by a community nurse who will visit 2- 3 times a week to drain the ascites. Informal caregivers can be trained to do this if they are willing. Those randomised to the LVP arm will attend the hospital for drainage of the ascites in line with the standard of care. All participants will also receive a fortnightly home visit from the research team for safety monitoring, routine clinical bloods, collection of LTAD drainage data collated by the community nurses and for completion of the questionnaires. In those randomised to LVP, if hospital visits coincide with the fortnightly home visits, the clinical bloods and questionnaire-based assessments can be performed at the hospital. There is also the option for all participants, their informal caregivers if they have one, and healthcare professionals to participate in a qualitative interview. This one-off interview is to gain a deeper understanding of the issues affecting the participants/caregivers/healthcare professionals and to gain a more in-depth understanding of views and perceptions of ascites drainage via the LTAD vs. LVP. The interviews will be conducted at a one-off time point during the 12 weeks they are in the study. There is also an optional research blood sample that if the patient's consent will be taken at the baseline visit and stored for analysis at the end of the study. This sample is purely for research purposes. This study has been supported by extensive Patient & Public Involvement (PPI) and Engagement and leads on from the work undertaken in the feasibility study. The group have helped shape the research methodology, outcome measures and assessment tools and is part of the research team. The service users will provide input throughout the trial. Bespoke training will be provided to the PPI.

Previous interventions:
Study design
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follow-up will be conducted across 35 sites in England and Scotland. We aim to recruit 310 patients. 30 patients, 20 informal caregivers and 20 healthcare professionals will also be invited to give their perceptions/perspectives of LTAD and LVP using qualitative methods.

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Intervention Type
Procedure/Surgery

Primary outcome measure
Liver-specific health-related quality of life (HRQoL) measured using the short-form-liver disease quality of life (SFLDQoL) questionnaire at 3 months

Secondary outcome measures
1. Cumulative incidence of peritonitis in the LTAD and LVP groups measured using standard laboratory methods at 12 weeks. Peritonitis defined as ascitic white cell count > 500 cells/mm3, and/or neutrophil count > 250 cells/mm3 and/or a positive ascitic fluid culture.
2. Ascites-related symptoms measured using the Ascites Q questionnaire at baseline and weeks 2, 4, 6, 8, 10 and 12
3. Workload impact on the caregiver assessed using the Caregiver Roles and Responsibilities Scale (CRRC) at baseline and weeks 4, 8 and 12
4.1. Health Resource Utilisation measured using the modified Ambulatory and Home Care Record (AHCR) for community service use at baseline and weeks 4, 8 and 12
4.2. Hospital service use measured using the Hospital Service use in-house designed questionnaire (to be completed by a member of the research team) at the week 12 visit
4.3 Cost-utility measured using the EQ-5D-5L questionnaire to generate adjusted life years (QALYs) at baseline and weeks 2, 4, 6, 8, 10 and 12

Overall study start date
01/05/2022

Completion date
30/09/2026

Eligibility

Key inclusion criteria
Current inclusion criteria as of 04/12/2024:

1. Aged 18 years old and over
2. Refractory ascites due to cirrhosis (with the need for one or more LVP per month), defined as per International Ascites Club criteria (5-6):
-Diuretic-resistant ascites: ascites that cannot be mobilized or the early recurrence of which cannot be prevented because of a lack of response to sodium restriction and diuretic treatment (spironolactone 400 mg and furosemide 160 mg) and or Diuretic-intractable ascites: ascites that cannot be mobilized or the early recurrence of which cannot be prevented because of the development of diuretic-induced complications that preclude the use of an effective diuretic dosage
3. Registered with a GP in the community Trusts served by the participating centres.
4. Capacity to give informed consent.

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Previous participant inclusion criteria as of 01/11/2023:

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Participant type(s)
Patient, Health professional, Carer, Mixed

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 310; UK Sample Size: 310

Key exclusion criteria
Current exclusion criteria as of 04/12/2024:

1. Loculated and or chylous ascites
2. 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
3. A candidate for liver transplantation and or TIPS
4. Psychosocial issues which in the opinion of the medical team will preclude study participation
5. Pregnancy - all women of childbearing age must have a negative pregnancy test
6. Lacks Capacity to give informed consent

Previous exclusion criteria:
1. Loculated and or chylous ascites
2. 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
3. A candidate for liver transplantation and or TIPS
4. Psychosocial issues which in the opinion of the medical team will preclude study participation
5. Pregnancy - all women of childbearing age must have a negative pregnancy test

Date of first enrolment
01/10/2022

Date of final enrolment
30/06/2026

Locations

Countries of recruitment
England

Scotland

United Kingdom

Wales

Study participating centre
Worthing Hospital
Lyndhurst Road
Worthing
United Kingdom
BN11 2DH

Study participating centre
Royal Devon and Exeter Hospital
Royal Devon & Exeter Hospital
Barrack Road
Exeter
United Kingdom
EX2 5DW

Study participating centre
Southampton
Southampton General Hospital
Tremona Road
Southampton
United Kingdom
SO16 6YD

Study participating centre
Derriford Hospital
Derriford Road
Derriford
Plymouth
United Kingdom
PL6 8DH

Study participating centre
Queen Elizabeth Hospital
Mindelsohn Way
Edgbaston
Birmingham
United Kingdom
B15 2GW

Study participating centre
Liverpool University Hospitals NHS Foundation Trust
Royal Liverpool University Hospital
Prescot Street
Liverpool
United Kingdom
L7 8XP

Study participating centre
Northern General Hospital
Northern General Hospital NHS Trust
C Floor, Huntsmnan Building
Herries Road
Sheffield
United Kingdom
S5 7AU

Study participating centre
Queens Medical Centre
Derby Road
Nottingham
United Kingdom
NG7 2UH

Study participating centre
St George's Hospital
Blackshaw Road
Tooting
London
United Kingdom
SW17 0QT

Study participating centre
St Thomas' Hospital (alliance Medical Scanning)
St. Thomas's Hospital
Westminster Bridge Road
London
United Kingdom
SE1 7EH

Study participating centre
Royal Free London NHS Foundation Trust
Royal Free Hospital
Pond Street
London
United Kingdom
NW3 2QG

Study participating centre
Norfolk and Norwich University Hospitals NHS Foundation Trust
Colney Lane
Colney
Norwich
United Kingdom
NR4 7UY

Study participating centre
Queen Alexandra Hospital
Southwick Hill Road
Cosham
Portsmouth
United Kingdom
PO6 3LY

Study participating centre
King's College Hospital NHS Foundation Trust
Denmark Hill
London
United Kingdom
SE5 9RS

Study participating centre
Hull Royal Infirmary
Anlaby Road
Hull
United Kingdom
HU3 2JZ

Study participating centre
The Royal Bolton Hospital
Minerva Road
Farnworth Bolton
Bolton
United Kingdom
BL4 0JR

Study participating centre
Freeman Hospital
Freeman Road
High Heaton
Newcastle upon Tyne
United Kingdom
NE7 7DN

Study participating centre
Gartnavel Royal Hospital
1055 Great Western Road
Glasgow
United Kingdom
G12 0XH

Study participating centre
Southmead Hospital
Southmead Road
Westbury-on-trym

Bristol
United Kingdom
BS10 5NB

Study participating centre
Royal Derby Hospital (nuh)
Uttoxeter Road
Derby
United Kingdom
DE22 3NE

Study participating centre
NHS Grampian
Summerfield House
2 Eday Road
Aberdeen
United Kingdom
AB15 6RE

Study participating centre
NHS Lanarkshire
14 Beckford Street
Hamilton
United Kingdom
ML3 0TA

Study participating centre
Royal Sussex County Hospital
Eastern Road
Brighton
United Kingdom
BN2 5BE

Study participating centre
North Tyneside General Hospital
Rake Lane
North Shields
United Kingdom
NE29 8NH

Study participating centre
Addenbrookes Hospital
Hills Road
Cambridge
United Kingdom
CB2 0QQ

Study participating centre
Gloucestershire Royal Hospital
Great Western Road
Gloucester
United Kingdom
GL1 3NN

Study participating centre
The Royal Glamorgan Hospital
Ynysmaerdy
Pontyclun
United Kingdom
CF72 8XR

Study participating centre
NHS Lothian
Royal Infirmary of Edinburgh
Waverley Gate
2-4 Waterloo Place
Edinburgh
United Kingdom
EH1 3EG

Study participating centre
The Royal London Hospital
Barts Health NHS trust
Whitechapel
London
United Kingdom
E1 1BB

Study participating centre

Royal Surrey County Hospital
Egerton Road
Guildford
United Kingdom
GU2 7XX

Study participating centre
New Cross Hospital Royal Wolverhampton
Wolverhampton Road
Heath Town
Wolverhampton
United Kingdom
WV10 0QP

Study participating centre
Gateshead Hospitals NHS Trust
Queen Elizabeth Hospital
Sherriff Hill
Gateshead
United Kingdom
NE9 6SX

Study participating centre
The James Cook University Hospital
Marton Road
Middlesbrough
United Kingdom
TS4 3BW

Study participating centre
Royal Cornwall Hospitals NHS Trust
Royal Cornwall Hospital
Treliske
Truro
United Kingdom
TR1 3LJ

Study participating centre
University Hospital of North Durham
North Road
Durham

United Kingdom
DH1 5TW

Sponsor information

Organisation
University of Sussex

Sponsor details
Sussex House
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Brighton
England
United Kingdom
BN1 9RH
+44 (0)1273872748
researchsponsorship@sussex.ac.uk

Sponsor type
University/education

Website
https://www.sussex.ac.uk/

ROR
https://ror.org/00ayhx656

Funder(s)

Funder type
Government

Funder Name
National Institute for Health and Care Research Evaluation, Trials and Studies Co-ordinating Centre (NETSCC); Grant Codes: NIHR133889

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
1. Peer-reviewed scientific journals
2. Internal report
3. Conference presentation
4. Publication on website
5. Other publication

No identifiable personal data will be used when publishing results, only annonymised data.

Intention to publish date
30/09/2027

Individual participant data (IPD) sharing plan
The data sharing plans for the current study are unknown and will be made available at a later date

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?
HRA research summary			28/06/2023	No	No
Protocol article		04/06/2025	09/06/2025	Yes	No