

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

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<b>Registration date</b> 15/08/2022	<b>Overall study status</b> Ongoing	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 09/06/2025	<b>Condition category</b> Digestive System	<input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> 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

**Contact name**

Prof Sumita Verma

**ORCID ID**

<https://orcid.org/0000-0001-7021-8409>

**Contact details**

University of Sussex  
Brighton and Sussex Medical School  
Main Teaching Building  
Room 2.17  
Falmer  
Brighton  
United Kingdom  
BN1 9PX  
+44 (0)1273 877890  
[s.verma@bsms.ac.uk](mailto:s.verma@bsms.ac.uk)

**Type(s)**

Public

**Contact name**

Ms Alison Porges

**Contact details**

Clinical Trial Manager  
Brighton & Sussex Clinical Trials Unit  
Room 111, Watson Building  
University of Brighton  
Brighton  
United Kingdom  
BN1 9PH  
None provided  
[a.porges@bsms.ac.uk](mailto:a.porges@bsms.ac.uk)

## 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

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 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/mm<sup>3</sup>, and/or neutrophil count > 250 cells/mm<sup>3</sup> 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:

1. Aged 18 years old and over
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3. 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

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4. Registered with a GP in the community Trusts served by the participating centres.

### **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
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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, Huntsman 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**

Marlon 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  
Falmer  
Southern Ring Road  
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 anonymised 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?
<a href="#">HRA research summary</a>			28/06/2023	No	No
<a href="#">Protocol article</a>		04/06/2025	09/06/2025	Yes	No