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Assessing experience, safety, and outcomes of the Passio Pump Drainage System

Submission date
19/02/2024

Recruitment status
No longer recruiting

Registration date
28/06/2024

Overall study status
Completed

Last Edited
11/07/2025

Condition category
Respiratory

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

Plain English summary of protocol

Background and study aims
The pleural membranes are two thin layers of tissue covering the outside of the lung. Excess fluid can accumulate between these layers (a pleural effusion) causing breathlessness. This fluid can be managed with a semi-permanent catheter called an indwelling pleural catheter (IPC). These IPCs are drained regularly at home to manage the patient's symptoms and prevent effusion recurrence.
If the effusion is drained regularly, the pleura can adhere together, preventing further fluid accumulation (autopleurodesis). Evidence suggests that more frequent drainage promotes more rapid pleurodesis and earlier IPC removal. Unfortunately, due to shortages of community nurses, patients are often drained 3 times weekly, rather than 5 times weekly, as is best practice.
Current drainage systems (the BD PleurX drainage system) use vacuum drainage bottles, which require considerable dexterity to use. This prohibits patients from managing their own drainages and increases the burden on community nurses, reducing patients' drainage frequency. It can be challenging to control drainage rates with bottles, which can be uncomfortable.
The Passio Pump Drainage System uses a handheld electronic pump to drain fluid from an IPC into a bag, offering electronic control of drainage. It is more portable and simpler to use, which could allow patients to manage their own drainages more frequently.
ESOP is a randomised-controlled, crossover, exploratory study being run at North Bristol NHS Trust, Bristol, UK. This study aims to gather information regarding the safety, tolerability and patient experience of the Passio Pump Drainage system compared to the BD PleurX drainage system.

Who can participate?
Patients aged 18 years and over with a recurrent symptomatic malignant pleural effusion requiring an IPC insertion for long-term management within the catchment area of North Bristol NHS Trust.

What does the study involve?
Participants will be randomly allocated to have inserted either a Passio catheter or a BD PleurX IPC (current standard IPC) with a 3-5 x weekly drainage regimen. They will keep a symptom and drainage diary, with reviews at 2 and 4 weeks to assess whether their effusion has dried up and the catheter can be removed. This study has the potential to inform further research using this

drainage system. Participants will spend the first 2 weeks of the study using the device to which they were randomly allocated, then will switch to the alternative device for the second 2 weeks of the study.

What are the potential benefits and risks of participating?
Everyone who takes part in the study will receive the benefits of having an IPC in place to help manage their symptoms associated with fluid that keeps building back up. If you receive the new drainage system you may be able to have a relative or carer drain your IPC, or drain the IPC yourself (after they/you have received training) rather than a nurse.
If you receive the new drainage system there is more control over the drainage which may reduce the chances of feeling discomfort or pain. The extra chest X-ray at the 2-week visit allows for closer monitoring of any changes to the volume of fluid around your lungs and may result in the IPC being removed early if the fluid is not building back up. Whichever group you are allocated to, your participation in this study will help improve our understanding of patients' experiences of different types of IPC, drainage devices and different drainage schedules. This will benefit patients in your situation in the future.
The study design requires you to have drainages 3-5 x weekly, which could be burdensome for some people. That said, the researchers believe that this drainage regimen will keep your symptoms as manageable as possible and may actually reduce the amount of time that the IPC needs to remain in place, allowing you to return to your normal activities sooner. Several of the chest X-rays required during this study would be needed anyway as part of your routine care. As part of the study, you may need to have 2-3 additional chest X-rays to provide us with a baseline chest X-ray if you haven't had one done recently and to assess whether your effusion has dried up (pleurodesed). Other risks/ disadvantages associated with taking part include attending an extra follow-up appointment 2 weeks after your IPC has been inserted.

Where is the study run from?
North Bristol NHS Trust (UK)

When is the study starting and how long is it expected to run for?
March 2022 to July 2025

Who is funding the study?
It is funded by Bearpac Plc (USA) who make the Bearpac Passio Pump Drainage System

Who is the main contact?
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Scientific, Principal investigator

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Additional identifiers

Integrated Research Application System (IRAS)
322486

Protocol serial number
5343

Study information

Scientific Title
Assessing experience, safety, and outcomes of the Passio Pump Drainage System – a randomised, controlled crossover, exploratory study

Acronym
AESOP

Study objectives
To gather preliminary data regarding the safety, efficacy and tolerability of the Passio Pump Drainage System in comparison to the BD PleurX Pleural Catheter System.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 14/02/2024, Liverpool Central (2 Redman Place, London, E20 1JQ, United Kingdom; +44 (0)207 104 8118; liverpoolcentral.rec@hra.nhs.uk), ref: 24/NW/0020

Primary study design
Interventional

Study design
Single-centre crossover 1:1 randomized controlled trial

Study type(s)
Quality of life, Safety, Efficacy

Health condition(s) or problem(s) studied
Malignant pleural effusion

Interventions
Participants will be randomised to IPC insertion with either a Bearpac Passio catheter or a standard catheter (BD PleurX). After 2 weeks, they will cross over to the alternative drainage system for a further 2 weeks so that all patients experience both drainage systems.

Follow-up will occur 2 and 4 weeks post IPC insertion, with data collected on patient-reported outcome measures, analgesia use, drainage volumes, the person performing each drainage, adverse events and additional comments the participants may have about their experience.

Randomisation will be by a randomisation module within the bespoke REDCap database for the project.

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Bearpac Passio catheter, standard catheter (BD PleurX)

Primary outcome(s)
1. Safety will be evaluated using the number and type of device related adverse events at 28 days post IPC insertion
2. Patient reported outcomes in terms of chest pain and breathlessness will be measured using the mean change in self-reported pain and breathlessness scores, measured pre- and post- each IPC drainage (3-5 x weekly)

Key secondary outcome(s)
The overall patient experience of study involvement and use of both devices will be evaluated in semi-structured interviews arranged at the participants' convenience following their 28 day follow up.

Completion date
17/07/2025

Eligibility

Key inclusion criteria
1. Confirmed presence of recurrent, symptomatic malignant effusion requiring long-term, intermittent drainage with an indwelling pleural catheter
2. Participant normally lives within the catchment area of North Bristol NHS Trust and is unlikely to relocate within 1 month
3. Aged 18 years or over
4. Able to provide informed consent

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Upper age limit
110 Years

Sex
All

Total final enrolment

22

Key exclusion criteria
1. Known or suspected pleural cavity infection or sepsis
2. Known or suspected uncorrected coagulopathy
3. Contraindication to indwelling pleural catheter insertion
4. Anticipated survival of less than 1 month
5. Patient is a prisoner or young offender in the custody of HM Prison Service or an offender supervised by the probation service in England or Wales

Date of first enrolment
01/06/2024

Date of final enrolment
17/06/2025

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
North Bristol NHS Trust
Southmead Hospital
Southmead Road
Westbury-on-trym
Bristol
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BS10 5NB

Sponsor information

Organisation
North Bristol NHS Trust

ROR
https://ror.org/036x6gt55

Funder(s)

Funder type

Industry

Funder Name
Bearpac Plc

Results and Publications

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