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REDUCE Trial: A randomised controlled trial evaluating the efficacy of indwelling pleural catheters in persistent non-malignant symptomatic pleural effusions

Submission date
15/07/2015

Recruitment status
No longer recruiting

Registration date
15/07/2015

Overall study status
Completed

Last Edited
07/04/2022

Condition category
Respiratory

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Some people with diseases affecting the function of the heart or liver can collect fluid in the space between the lung and the chest wall (a pleural effusion). The amount of fluid that builds up varies. If the amount of large enough, it can press on the lung, stopping it from expanding fully as the patient breathes and causing breathlessness. Treatment varies greatly as it largely depends on the underlying cause. However, there is limited guidance on how to treat the effusion directly. This study will compare two treatment methods: removal of the fluid with a needle and syringe as and when needed (control) or insertion of an indwelling pleural catheter through which fluid can be removed in the patients home by means of vacuum filled bottles, usually by district nurses.

Who can participate?
Adults (at least 18) with a pleural effusion resulting from heart or liver disease.

What does the study involve?
Participants are randomly allocated into one of two groups. Those in group 1 are treated using the needle and syringe method. Those in group 2 are treated via the pleural catheter method. Levels of breathlessness, quality of life and the cost and complications of treatment are then compared between the two groups.

What are the possible benefits and risks of participating?
All patients in the trial will have fluid taken off from around their lungs which should improve their breathing. Both treatments have some potential risks, including bleeding, infection or discomfort. We will limit these by making sure patient's blood is clotting normally before any procedure, making sure that procedures are done in a clean environment with clean equipment and using a numbing injection before doing any procedure and using pain-killers after the procedure if patients have any pain. Patients will have regular contact with study doctors to ensure that any problems are picked up as early as possible. Patients with fluid around the lung

often need chest x-rays to monitor the fluid, however patients in this study will require two additional chest X-rays, at the beginning of the trial and at the 12 week follow up visit. There is a small theoretical risk with this extra radiation; however chest x-rays are associated with a low level of radiation. Two X-rays are equivalent to one and a half weeks of background radiation in the UK.

Where is the study run from?
The lead centre for this study is North Bristol NHS Trust. We aim to run the trial from a total of 11 centres in England. Centres will be chosen on the basis of whether they have experience with this sort of trial and have the access to the right specialists and procedures.

When is the study starting and how long is it expected to run for?
January 2015 to August 2016

Who is funding the study?
CareFusion Corporation

Who is the main contact?
Prof Nick Maskell
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Contact information

Type(s)
Public

Contact name
Prof Nick Maskell

ORCID ID
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Contact details
Southmead Hospital
Southmead Road
Westbury-On-Trym
Bristol
United Kingdom
BS10 5NB

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
17127

Study information

Scientific Title
A randomised controlled trial evaluating the efficacy of indwelling pleural catheters in persistent non-malignant symptomatic pleural effusions

Acronym
REDUCE

Study objectives
This study aims to compare two methods to treat pleural effusion; removal of the fluid with a needle and syringe as and when needed (control) or insertion of an indwelling pleural catheter through which fluid can be removed in the patients home by means of vacuum filled bottles.

Ethics approval required
Old ethics approval format

Ethics approval(s)
NRES Committee South West - Central Bristol, 01/05/2015, ref: 14/SW/0075

Study design
Randomised; Interventional; Design type: Treatment

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 contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Topic: Respiratory disorders; Subtopic: Respiratory (all Subtopics); Disease: Respiratory

Interventions
1. Insertion of indwelling pleural catheter at randomisation, three times weekly drainage for 2 weeks then drainage as frequently as clinically required
2. Therapeutic aspiration at baseline and further therapeutic aspirations as clinically required
Follow Up Length: 3 month(s); Study Entry : Registration only

Intervention Type
Other

Primary outcome measure
Change in breathlessness (VAS score); Timepoint(s): Change to VAS over 12 week trial period

Secondary outcome measures
1. Adverse events related to trial intervention; Timepoint(s): 12 weeks
2. Albumin levels in patients with liver disease; Timepoint(s): 12 weeks
3. Cost effectiveness; Timepoint(s): 12 weeks
4. Failure of initially randomised treatment; Timepoint(s): 12 weeks
5. Health related quality of life (EQ-5D); Timepoint(s): 12 weeks
6. Hospital visits and bed days; Timepoint(s): 12 weeks
7. Number of pleural interventions; Timepoint(s): 12 weeks
8. Pleurodesis; Timepoint(s): 12 weeks; Volume of fluid drained; Timepoint(s): 12 weeks
9. Volume of fluid drained; Timepoint(s): 12 weeks

Overall study start date
09/01/2015

Completion date
31/08/2017

Eligibility

Key inclusion criteria
1. Clinically confident diagnosis of non-malignant pleural effusion secondary to either advanced stage CHF or liver failure requiring and amenable to pleural intervention for relief of breathlessness
2. Assessment by a cardiologist or hepatologist determining the presence of established heart failure or liver failure and a pleural effusion that persists despite optimised medical therapy
3. At least one previous therapeutic aspiration of pleural fluid with results consistent with the cause of the effusion being due to CHF or liver failure either:
3.1. a transudate by Light’s criteria in cases of effusions due to liver failure OR
3.2. either a transudate in effusions due to CHF or an exudate in cases where diuretics have been used and CHF can confidently be stated to be the cause
4. No evidence of malignancy on pleural fluid cytology
5. Expected survival >12 weeks
6. Written informed consent to trial participation
7. Target Gender: Male & Female
8. Lower Age Limit 18 years

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 86; UK Sample Size: 86; Description: Anticipated 8% loss to follow up.

Total final enrolment
68

Key exclusion criteria
1. Age <18 years
2. Known pleural malignancy
3. Pleural fluid pH < 7.2
4. Previously sited indwelling pleural catheter on the side requiring intervention or current indwelling pleural catheter on the contralateral side
5. Pregnancy, lactation or intention to become pregnant
6. Inability to give informed consent
7. Absolute contraindication to IPC or therapeutic aspiration of pleural fluid
8. Patient has no access to a telephone

Date of first enrolment
01/04/2015

Date of final enrolment
01/04/2017

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Southmead Hospital (lead centre)
Southmead Road
Westbury-On-Trym
Bristol
United Kingdom
BS10 5NB

Study participating centre
Medway NHS Foundation Trust
Windmill Rd
Gillingham
United Kingdom
ME7 5NY

Study participating centre
Guy's and St Thomas' NHS Foundation Trust
London
United Kingdom
SE1 7EH

Study participating centre
Cambridge University Hospitals
Cambridge
United Kingdom
CB2 0QQ

Study participating centre
South Tees Hospitals NHS Foundation Trust
Middlesbrough
United Kingdom
TS4 3BW

Study participating centre
North Tees and Hartlepool Hospitals NHS Foundation Trust
Middlesbrough
United Kingdom
TS1 98PE

Study participating centre
Oxford University Hospitals NHS Trust
Oxford
United Kingdom
OX3 9DU

Sponsor information

Organisation
North Bristol NHS Trust

Sponsor details
Research & Innovation
Floor 3 Learning & Research Building
Southmead Hospital

Bristol
England
United Kingdom
BS10 5NB

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/036x6gt55

Funder(s)

Funder type
Industry

Funder Name
CareFusion Corporation

Results and Publications

Publication and dissemination plan
Following completion of the study data from all centres will be analysed and published as soon as reasonably possible. Data will be submitted to a peer-reviewed medical journal within 1 year of trial completion for publication.

Intention to publish date

Individual participant data (IPD) sharing plan
Not added at the time of registration

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		24/02/2022	07/04/2022	Yes	No
HRA research summary			28/06/2023	No	No