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A randomised controlled trial of the use of a dedicated ballooned intercostal drain

Submission date 03/01/2018	**Recruitment status** No longer recruiting	[X] Prospectively registered [X] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 11/01/2018	**Overall study status** Completed	
Last Edited 28/02/2024	**Condition category** Respiratory	

Plain English summary of protocol

Background and study aims
The use of a tube inserted between the ribs (intercostal drain) to remove air or fluid from around the lung is an essential tool in the management of respiratory patients. A common complication of drain insertion is accidental removal of the drain, usually as a result of inadequate securing techniques. This often results in the need for further medical or surgical procedures (including drain re-siting), with associated additional risk to the patient and an increase in healthcare costs. One suggested method to reduce premature drain removal is to use intercostal drains with ballooned tips. The balloon would then provide a relatively harmless physical obstruction to the drain insertion site. A small study of the new drains suggested that there was a reduced need for further procedures without causing any additional discomfort or problems. The aim of this study is to find out whether the use of a dedicated ballooned intercostal drain leads to a reduction in drain re-siting rates.

Who can participate?
Patients aged 18 or over who require intercostal tube drainage

What does the study involve?
Participants are randomly allocated to either the new treatment (dedicated ballooned intercostal drain) or to standard care (conventional chest drain). The rates of unintentional /accidental chest drain displacement in the two groups are compared. Pain is also assessed to ensure that irritation of the lining of the lung and chest wall is not prohibitive.

What are the possible benefits and risks of participating?
It is hoped that the new chest drain is more secure and less likely to become dislodged or fall out, which means that the treatment may be more effective and may reduce the chances of needing another chest drain inserting. It is not anticipated that there will be any specific risks or disadvantages over standard medical care, other than the possibility that the balloon on the end of the drain could cause some irritation to the lining of the lung and chest wall. This may cause some discomfort. Risks associated with putting in any chest drain include:
1. Infection - as with any invasive procedure, there is a risk of infection. Using sterile procedures helps reduce this risk.
2. Bleeding - a very small amount of bleeding can occur if a blood vessel is damaged when the

chest tube is inserted.
3. Poor tube placement - the chest drain can be placed too far inside the pleural space, not far enough, or can fall out.
Serious complications are rare. However, they can include: bleeding into the chest cavity, injury to the lung or diaphragm, and pneumothorax (punctured lung). Participants have at least one chest x-ray after the drain is inserted and another before the drain is removed, but these would be needed whether they are in the study or not. A chest x-ray involves a very small amount of ionising radiation which is equivalent to 4 days of natural background radiation. Ionising radiation can cause cell damage that may, after many years or decades, turn cancerous. The chance of this happening is less than 0.001%, and is the same whether they take part in this study or not.

Where is the study run from?
1. Royal Brompton Hospital (UK)
2. King's Mill Hospital (UK)
3. John Radcliffe Hospital (UK)
4. Churchill Hospital (UK)
5. Southmead Hospital (UK)
6. Musgrove Hospital (UK)
7. Wythenshawe Hospital (UK)
8. Norwich and Norfolk NHS Foundation Trust (UK)
9. Plymouth Hospitals NHS Trust (UK)
10. Royal Stoke University Hospital (UK)
11. Glenfield Hospital (UK)
12. Victoria Hospital (UK)

When is the study starting and how long is it expected to run for?
September 2017 to July 2020

Who is funding the study?
Rocket Medical PLC (UK)

Who is the main contact?
Dr Rachel Mercer

Contact information

Type(s)
Scientific

Contact name
Dr Rachel Mercer

ORCID ID
http://orcid.org/0000-0003-3645-3151

Contact details
Oxford Respiratory Trials Unit
Churchill Hospital
Old Road
Oxford

United Kingdom
OX3 8HZ

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
36669

Study information

Scientific Title
A randomised controlled trial of the use of a dedicated ballooned intercostal drain

Acronym
BASIC

Study objectives
The use of a tube inserted between the ribs (intercostal drain) to remove air or fluid from around the lung is an essential tool in the management of respiratory patients. A common complication of drain insertion is accidental removal of the drain, usually as a result of inadequate securing techniques. This often results in the need for further medical or surgical procedures (including drain re-siting), with associated additional risk to the patient and an increase in health care costs. One suggested method to reduce premature drain removal is to use intercostal drains with ballooned tips. The balloon would then provide a relatively atraumatic physical obstruction to the drain insertion site.

A small trial of the new drains suggested that there was a reduced need for further procedures without causing any additional discomfort or problems. The trialists propose a randomised controlled trial (i.e. patients are randomly assigned to either the new treatment or to standard care) of a dedicated ballooned intercostal drain to investigate whether a reduction in drain re-siting rates can be achieved. Pain scores will also be assessed during this trial to ensure that irritation of the lining of the lung and chest wall is not prohibitive.

Ethics approval required
Old ethics approval format

Ethics approval(s)
South Central Oxford B, 15/12/2017, ref: 17/SC/0607

Study design
Randomised; Interventional; Design type: Treatment, Device

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
See additional files

Health condition(s) or problem(s) studied
Intercostal drain

Interventions
Randomisation will be via an online platform and will be 1:1, minimised by site and underlying aetiology. The standard arm will be insertion of a conventional chest drain as per standard British Thoracic Society Guidelines. The Interventional arm will have a chest drain with a balloon on the shaft which will be inflated once in the pleural cavity. Both arms will be monitored for unintentional drain displacement, timing of drain removal, pain and any complications. The time that the drain is in situ is variable but is usually under 1 week. All patients will be followed up at 30 days after drain removal.

Intervention Type
Procedure/Surgery

Primary outcome measure
Unintentional/accidental chest drain displacement rate (UACDR); Timepoint(s): Within 30 days

Secondary outcome measures
1. Pain, measured using the visual analogue scale (VAS) at baseline then twice daily for the first 5 days or until the drain has been removed, whichever is sooner
2. Complications listed on the CRFs and to be recorded daily on the CRFs
3. Length of stay, further pleural procedures, number of days any chest drain in situ, number of radiological investigations, consequences of drain displacement, documented on CRFs up to 30 days after drain removal

Overall study start date
06/09/2017

Completion date
20/12/2019

Eligibility

Key inclusion criteria
1. Age 18 years or over
2. Able to give written informed consent
3. Requiring intercostal tube drainage for clinical reasons

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 267; UK Sample Size: 267

Total final enrolment
267

Key exclusion criteria
1. Inability to provide written informed consent
2. Requiring a large bore drain according to local PI or delegated person's clinical judgement
3. Frank haemothorax (requiring a large bore chest drain in view of the local PI or delegated person)
4. Pleural space (known prior to intervention) to be too small to place either standard or interventional drain according to local PI or delegated person
5. Drain planned to be in situ for less than 24 hours
6. Any contraindication to chest drain insertion (such as uncorrected clotting abnormality)
7. Any patient in acute pain or with an emergency presentation where consideration of the study would inappropriately delay patient care

Date of first enrolment
15/02/2018

Date of final enrolment
13/11/2019

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Royal Brompton Hospital
Sydney Street

London
United Kingdom
SW3 6NP

Study participating centre
King's Mill Hospital
Mansfield Road
Sutton-in-Ashfield
United Kingdom
NG17 4JL

Study participating centre
Oxford University Hospitals NHS Foundation Trust
John Radcliffe Hospital (lead site, also Churchill Hospital)
Headley Way
Oxford
United Kingdom
OX3 9DU

Study participating centre
North Bristol NHS Trust
Southmead Hospital
Westbury-on-Trym
Bristol
United Kingdom
BS10 5NB

Study participating centre
Taunton and Somerset NHS Foundation Trust
Musgrove Hospital
Taunton
United Kingdom
TA1 5DA

Study participating centre
University Hospital of South Manchester NHS Foundation Trust (Wythenshawe Hospital)
Southmoor Road
Wythenshawe
Manchester
United Kingdom
M23 9LT

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

Study participating centre
Plymouth Hospitals NHS Trust
Derriford Road
Crownhill
Plymouth
United Kingdom
PL6 8DH

Study participating centre
University Hospitals of North Midlands NHS Trust (Royal Stoke University Hospital)
Newcastle Road
Stoke-On-Trent
United Kingdom
ST4 6QG

Study participating centre
University Hospitals of Leicester NHS Trust (Glenfield Hospital)
Gwendolen Road
Leicester
United Kingdom
LE5 4QF

Study participating centre
Blackpool Teaching Hospitals NHS Foundation Trust
Victoria Hospital
Whinney Heys Road
Blackpool
United Kingdom
FY3 8NR

Sponsor information

Organisation
Royal Brompton & Harefield NHS Foundation Trust

Sponsor details
c/o Patrik Pettersson
Non-Commercial Research Business Manager
Royal Brompton Hospital
Sydney Street
London
England
United Kingdom
SW3 6NP

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/02218z997

Funder(s)

Funder type
Industry

Funder Name
Rocket Medical PLC

Results and Publications

Publication and dissemination plan
The protocol will be submitted for publication. The aim is to publish the results in national and international journals within a year of complete data collection.

Intention to publish date
20/12/2020

Individual participant data (IPD) sharing plan
The datasets generated and/or analysed during the current study during this study will be included in the subsequent results publication.

IPD sharing plan summary
Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version V2.0	24/11/2017	11/01/2018	No	Yes
Abstract results		28/10/2020	04/03/2022	No	No
HRA research summary			28/06/2023	No	No
Protocol file	version 7.0	03/04/2019	28/02/2024	No	No
Results article		21/07/2022	28/02/2024	Yes	No