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The efficacy of Indwelling Pleural Catheter placement versus IPC placement PLUS sclerosant (talc) in patients with malignant pleural effusions managed exclusively as out-patients

Submission date
23/08/2012

Recruitment status
No longer recruiting

Registration date
23/08/2012

Overall study status
Completed

Last Edited
26/10/2022

Condition category
Cancer

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

Plain English summary of protocol

Background and study aims

Many people with cancer develop a build-up of fluid in the space between the lung and the chest wall, known as the pleural space. This may be due to a tumour which directly affects the lung lining (the pleura) or another cancer from elsewhere which spreads to affect the pleura. If enough fluid accumulates the lung can be compressed, making patients feel breathless. This fluid is called a malignant pleural effusion. The traditional method for dealing with this fluid is to admit the patient to hospital and insert a chest tube into the space around the lung where the fluid has built up, which allows the fluid to be drained away, improving symptoms. However, this fluid may build up again after the tube is removed. This usually takes some time but can occur in only a few days. In order to try and prevent this, an irritant substance such as talc powder can be inserted through the chest tube. This aims to cause the two sides of the pleural space to stick together which prevents further fluid build-up, and is called pleurodesis. Whilst often relatively successful, this method of pleurodesis can be inconvenient for patients as they often need to be in hospital for at least 5 days. In recent years an alternative method has become available. This involves the insertion of a chest tube which is tunnelled under the skin, and hence can stay in place for much longer. Their main benefit is that they can be inserted as an outpatient and as more fluid builds up it can be tapped off using the drain as needed by community nurses. In the United States, these indwelling pleural catheters (IPC) are often the first line of treatment for malignant pleural effusions. Another benefit is that if left long enough, these tubes can also cause the pleural surfaces to adhere to each other and so may actually prevent further fluid build-up in much the same way as talc can. The rate of pleurodesis, however, is not as high as with talc, and if used for more than a few weeks the cost of using the IPC begins to exceed that of traditional treatment. This study aims to find out the best way of treating patients with malignant pleural effusions by treating people with a combination of both indwelling pleural catheter and talc instillation. We shall measure the rates of pleurodesis after five weeks compared with patients treated with just a pleural catheter alone. In theory, the addition of talc

should allow the catheters to be removed more quickly. Although this study will look at patients from the UK, the results will be applicable globally and may help to change the way in which malignant pleural effusions are managed.

Who can participate?
Adult patients with a malignant pleural effusion that is suitable for insertion of an indwelling pleural catheter.

What does the study involve?
All participants receive an IPC as per normal practice, which is drained at least twice per week. After 10 days a chest x-ray is performed to ensure that the lung has fully expanded and the fluid has been drained away. If this is the case, patients are randomly allocated to receive either a mixture containing talc powder or a placebo (an inert/dummy substance) through their IPC. Patients are then followed up for 10 weeks at 2-weekly intervals, with IPC drainage continuing. At each appointment, patients will have a chest x-ray, an ultrasound scan of the chest, and will be asked to fill out questionnaires about their quality of life. For the duration of the study, patients are asked to keep a record of how much pain and breathlessness they are feeling using a chart. Participants are also asked to provide samples of blood and pleural fluid during the trial, although they can opt out of this if they choose.

What are the possible benefits and risks of participating?
All patients should experience the benefits of having an indwelling pleural catheter in place, so that breathlessness can be relieved quickly and easily. IPCs can lead to short-term soreness around the insertion site, although this is easily managed with painkillers. Talc is a safe and widely-used substance. Some patients may experience a small amount of pain and/or a fever after administration but this may also be controlled with simple painkillers. We do not expect any extra risks from the combination of the two treatments, but we do hope that those who receive talc will have the benefit of quicker, more successful pleurodesis.

Where is the study run from?
18 NHS hospitals in England, with the main centre being Southmead Hospital in North Bristol

When is the study starting and how long is it expected to run for?
June 2012 to March 2016

Who is funding the study?
CareFusion (USA)

Who is the main contact?
Dr Nick Maskell
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https://www.cancerresearchuk.org/about-cancer/find-a-clinical-trial/a-trial-comparing-2-ways-treating-build-up-of-fluid-around-lung-ipc-plus

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
2012-000599-40

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
12669

Study information

Scientific Title
The efficacy of Indwelling Pleural Catheter placement versus IPC placement PLUS sclerosant (talc) in patients with malignant pleural effusions managed exclusively as out-patients

Acronym
IPC-PLUS

Study objectives

Many types of cancer can affect the lining of the lung (the pleura). When this happens fluid can build up between the pleura which can then compress the underlying lung, causing breathlessness. The management of this malignant pleural fluid, or effusion, can be difficult as there is often a tendency for it to recur.

Traditional management of malignant effusions involves inserting a chest tube into the fluid to allow it to be drained away. Once this is done an irritant substance such as sterile talc is inserted through the tube. This causes inflammation, which in turn causes the pleura to stick together, preventing further fluid build-up. This is called pleurodesis. Although successful in about 85% of cases, this method can be cumbersome for patients and often involves a hospital stay of up to a week.

A more recent development is the indwelling pleural catheter (IPC). This type of chest tube is inserted as a day case procedure, and is tunnelled under the skin to reduce the risk of infection. Once in place, any fluid which builds up can be tapped off in the patient's own home. This approach is generally more convenient for patients and can also lead to pleurodesis, although the rates for this are lower than with talc at around 50%.

The IPC-PLUS trial aims to determine the optimum management of patients with malignant pleural effusions by using a combination of both IPC and talc for the first time. We shall compare pleurodesis rates, as well as patients' quality of life and breathlessness, with those treated with an IPC and an inert placebo. Although this study will look at patients from the UK, the results will be applicable globally and may help to change the way in which malignant pleural effusions are cared for.

Ethics approval required
Old ethics approval format

Ethics approval(s)
First MREC, 24/05/2012, ref: 12/SC/0242

Study design
Randomised interventional trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

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

Health condition(s) or problem(s) studied

Lung cancer

Interventions
Administration of IMP/placebo.

Randomisation to receive either sterile talc or placebo through an already placed indwelling pleural catheter

Intervention Type
Procedure/Surgery

Primary outcome measure
Number of patients with successful pleurodesis measured at 5 Weeks

Secondary outcome measures
No secondary outcome measures

Overall study start date
26/06/2012

Completion date
31/03/2016

Eligibility

Key inclusion criteria
1. Symptomatic malignant pleural effusion, agreed at appropriate local / regional MDT to require IPC, defined as pleural fluid in the context of:
1.1. Histocytologically proven pleural malignancy, OR
1.2. Otherwise unexplained pleural effusion in the context of clinically proven cancer elsewhere, OR
1.3. Radiologically proven pleural malignancy as diagnosed in normal clinical practice on thoracic CT in the absence of histocytological proof
2 .Expected survival greater than 2 months
3. Written informed consent to trial participation.
4. Male or female participants
5. Lower Age Limit 18 years

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
UK Sample Size: 154

Total final enrolment
154

Key exclusion criteria
1. Age < 18 years
2. Females who are pregnant or lactating
3. Patient unable to provide informed consent
4. Previous attempts at pleurodesis on same side as effusion requiring management
5. Previously documented adverse reaction to talc or lidocaine
6. Community services unable to drain indwelling pleural catheter at least twice per week
7. Evidence of extensive lung entrapment on CXR or CT, or significant fluid loculation on ultrasound scan, to a level which would normally be a contraindication to attempted talc pleurodesis or IPC insertion
8. Other contraindication to indwelling pleural catheter insertion

Date of first enrolment
26/06/2012

Date of final enrolment
31/03/2016

Locations

Countries of recruitment
England

United Kingdom

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

Study participating centre
Churchill Hospital
Oxford University Hospitals NHS FT
Headington
Oxford
United Kingdom
OX3 7LE

Study participating centre
Great Western Hospital
Great Western Hospitals NHS Trust
Marlborough Road
Swindon
United Kingdom
SN3 6BB

Study participating centre
Royal Preston Hospital
Lancashire Teaching Hospitals NHS Trust
Fulwood
Preston
United Kingdom
PR2 9HT

Study participating centre
Queen Alexandra Hospital
Portsmouth Hospitals NHS Trust
Cosham
Portsmouth
United Kingdom
PO6 3LY

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

Study participating centre
Wythenshawe Hospital
University Hospital of South Manchester NHS FT
Southmoor Road
Wythenshawe
Manchester
United Kingdom
M23 9LT

Study participating centre
Worcestershire Royal Hospital
Worcestershire Acute Hospitals NHS Trust
Charles Hastings Way
Worcester
United Kingdom
WR5 1DD

Study participating centre
North Tyneside General Hospital
Northumbria Healthcare NHS FT
Rake Lane
North Shields
United Kingdom
NE29 8NH

Study participating centre
The James Cook University Hospital
South Tees Hospitals NHS FT
Marton Road
Middlesbrough
United Kingdom
TS4 3BW

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

Study participating centre
University Hospital of North Tees
North Tees and Hartlepool NHS Foundation Trust
Hardwick
Stockton
United Kingdom
TS19 8PE

Study participating centre
Guy's & St Thomas' Hospital
Guy's and St Thomas' NHS Foundation Trust
Westminster Bridge Road
London
United Kingdom
SE1 7EH

Study participating centre
King's Mill Hospital
Sherwood Forest Hospitals NHS Foundation Trust
Mansield Road
Sutton-in-Ashton
Nottingham
United Kingdom
NG17 4JL

Study participating centre
Royal United Hospital Bath
Royal United Hospital Bath NHS Trust
Combe Park
Bath
United Kingdom
BA1 3NG

Study participating centre
University Hospital Aintree
Aintree University Hospital NHS Foundation Trust
Liverpool
United Kingdom
L9 7AL

Study participating centre
University Hospital Crosshouse
NHS Ayrshire and Arran
Kilmarnock
United Kingdom
KA2 OBE

Study participating centre

Addenbrooke's Hospital
Cambridge University Hospitals NHS Foundation Trust
Hills Road
Cambridge
United Kingdom
CB2 0QQ

Sponsor information

Organisation
North Bristol NHS Trust (UK)

Sponsor details
Trust Headquarters
Beckspool Road
Frenchay
Bristol
England
United Kingdom
B16 1JE

Sponsor type
Hospital/treatment centre

Website
http://www.nbt.nhs.uk/

ROR
https://ror.org/036x6gt55

Funder(s)

Funder type
Industry

Funder Name
CareFusion Corporation (UK)

Results and Publications

Publication and dissemination plan

The protocol will be published in an open access journal. The full trial results will be published in peer reviewed journals and presented at national and international conferences. Trial results will also be disseminated to appropriate patient groups/charities upon completion.

Intention to publish date

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are/will be available upon request

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	12/02/2015		Yes	No
Results article	results	05/04/2018		Yes	No
Plain English results			26/10/2022	No	Yes
HRA research summary			28/06/2023	No	No