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A trial looking at thoracoscopy and talc versus indwelling pleural catheters plus thoracoscopy and talc for management of malignant pleural effusion

Submission date
02/08/2021

Recruitment status
No longer recruiting

Registration date
23/08/2021

Overall study status
Completed

Last Edited
07/07/2025

Condition category
Cancer

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

Plain English summary of protocol

Background and study aims
Patients with cancer can develop fluid around the lung as part of their illness. This is called a malignant pleural effusion. The pleura are thin layers that cover the outside surface of the lung. Fluid build-up between these layers can compress the lung and cause breathlessness. This study will compare one way of managing malignant pleural effusions with another.
A current method for managing fluid build-up is a procedure called a thoracoscopy, to drain away the fluid using a chest tube to improve breathlessness. Talc powder can be given at the same time to 'stick' the layers of the pleura together in order to 'dry up' or stop the fluid from returning. This is called a talc pleurodesis.
However, even despite a talc pleurodesis, the fluid may reaccumulate causing recurrent breathlessness in up to 25% of patients. If this happens, a second procedure to insert an indwelling pleural catheter (IPC) is often required. IPCs are flexible chest tubes that can remain in place as long as needed and allow drainage of the pleural effusion at home.
This study combines a thoracoscopy and talc pleurodesis with an IPC insertion in the same procedure. The researchers will compare this to a thoracoscopy and talc pleurodesis alone. They want to know whether this is better for patients in terms of their symptoms of breathlessness and the overall time they spend in hospital.

Who can participate?
Adults (aged 18 years or over) with a pleural effusion due to cancer, who require a thoracoscopy procedure.

What does the study involve?
Patients will be randomly allocated to either receive an indwelling pleural catheter (IPC) in the same procedure as the thoracoscopy and talc, or to receive a thoracoscopy and talc alone. The researchers are not able to influence or predict which procedure they receive. This is so they can be fairly compared. Treatment allocation will either happen before the procedure (if tests have already confirmed that the fluid build-up is due to cancer) or during the thoracoscopy procedure

(if cancer is suspected and to be confirmed depending on findings at the thoracoscopy).
During the thoracoscopy, patients will have a tube ('chest drain') inserted to drain the fluid. Talc will be given during the thoracoscopy or shortly after to try to stop the fluid from returning. Patients are likely to be admitted to the hospital for 48-72 hours after the procedure. The chest drain will be removed when there is no more fluid draining. Following this patients will be discharged home.
If patients receive an IPC, this will be inserted in addition during the thoracoscopy procedure. Patients in this group may be able to return home on the day of the procedure, once the chest drain (also inserted during the thoracoscopy procedure) is removed, if the medical team feels this is the right thing to do. Patients will go home with the IPC in place. A nurse will visit and drain any fluid from the IPC a minimum of 5 days a week over the first 2 weeks after the procedure. Regular IPC drainage improves the chances of the lung 'sticking' to the chest wall to prevent the fluid from returning.
All patients will be given a diary to complete to monitor their progress after the procedure. The diary includes simple questionnaires about how much breathlessness and chest pain (if any) patients are experiencing. This should only take a minute to complete and will be recorded twice per week. Patients will also be asked to use the diary to record any appointments or discussions with healthcare providers. In addition, there is space for patients who have an IPC to record how much fluid is drained at each district nurse visit.
The researchers will monitor the patients' progress over the next 12 weeks. Follow-up visits will take place at 2 weeks, 4 weeks and 12 weeks after the procedure.
As an optional aspect of the study, patients' primary carers will be invited to complete some simple questionnaires about the impact of being a carer. In addition, both the patient and their carer will be invited to take part in an interview together about the experience of the study and the treatments given. Both of these aspects are optional. Patients may take part in the study without agreeing for their carer to complete the questionnaires or taking part in the interview.

What are the possible benefits and risks of participating?
It is hoped that all patients find their symptoms are improved by whichever treatment they receive. Participating in this study will contribute to our understanding of the best way to treat patients with a malignant pleural effusion and shape the way other people are treated in the future. Patients who have an IPC inserted may be able to go home earlier after thoracoscopy than those who have thoracoscopy and talc alone. However, this is one of the questions that the researchers are trying to answer and they are not able to influence or predict which treatment patients receive.
Patients allocated to the 'standard care' group, who do not receive an IPC as part of the study will be treated in the same way as any other patient if the pleural effusion reaccumulates after the thoracoscopy and talc. There is no reason why they cannot have an IPC inserted with a second procedure if required. Alternatively, patients may receive an IPC as part of the trial and find that there is very little fluid being drained. However, it can easily be removed if this is the case. Medical teams will have advised patients about the specific risks involved with thoracoscopy, talc and IPC procedures as part of standard care. All patients taking part in the study will be carefully monitored during and after the procedure, and any important adverse events reported to the team running the trial. Taking part in this study involves having chest x-rays. Some of these will be extra to those if not taking part in the study. These procedures use ionising radiation to form images of the body. Ionising radiation may cause cancer many years or decades after the exposure. We are all at risk of developing cancer during our lifetime. The normal risk is that this will happen to about 50% of people at some point in their life. Taking part in this study will add only a very small chance of this happening.

Where is the study run from?
North Bristol NHS Trust and Oxford University Hospitals (UK)

When is the study starting and how long is it expected to run for?
March 2018 to April 2024

Who is funding the study?
National Institute of Health Research (NIHR) (UK)

Who is the main contact?
Prof. Nick Maskell
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Contact information

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Scientific

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Public

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
289120

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
CPMS 49804

Study information

Scientific Title
The randomised thoracoscopic talc poudrage and indwelling pleural catheters versus thoracoscopic talc poudrage only in malignant pleural effusion trial

Acronym
TACTIC

Study objectives
This study aims to compare two treatments for the management of fluid build-up around the lung (pleural effusion) caused by cancer. When this happens, the fluid can compress the lung, causing breathlessness. A standard way of managing the pleural effusion is by using a tube (called a chest drain) to remove the fluid and relieve breathlessness. A powder called talc can be used to stick the outside layers of the lung lining together to stop the fluid from returning after it has been drained away (called a pleurodesis). Both of these steps can be done during a thoracoscopy procedure.

In around 25% of patients the fluid can return after drainage, even despite the use of talc. If this happens, an indwelling pleural catheter (IPC) can be placed. This is a small, rubber tube inserted into the chest, which can remain in place for as long as required. It allows the fluid to be drained away regularly at home, without the need to return to hospital for further invasive procedures.

This study combines thoracoscopy and talc pleurodesis with IPC insertion in the same procedure. The researchers want to know whether this is better for patients in terms of their symptoms (breathlessness) and overall amount of time they spend in hospital compared to a thoracoscopy and talc pleurodesis alone.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 07/09/2021, London – Brent Research Ethics Committee (80 London Road, Skipton House, London, SE1 6LH, United Kingdom; +44 (0)207 1048 129; brent.rec@hra.nhs.uk), ref: 21/LO/0495

Study design
Randomized; Interventional; Design type: Treatment, Management of Care

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 participant information sheet

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

Interventions
Patients with a malignant pleural effusion will be identified from clinic lists, procedure lists and inpatient wards by clinicians working in pleural services. Patients will be screened using the inclusion and exclusion criteria and invited to participate in the study. Participation in the trial will be discussed and trial-specific patient information sheets given. Patient representatives have reviewed and given feedback on the patient information sheets to ensure that they give an understandable description of the patient journey through the trial.

Written, informed agreement (consent) will be obtained prior to enrolment and patients will be given as much time as needed to consider the information. Patients will also be given the option of participating in joint patient/carer interviews and for their primary carer/family member to complete questionnaires. Patients will be advised that choosing not to participate in these optional study aspects has no effect on continuing with trial involvement or their medical care.

Baseline assessments prior to randomisation will include a chest ultrasound, chest x-ray and blood tests. These tests are routine for all patients having a thoracoscopy procedure. Patients will be asked to complete quality of life questionnaires. All patients will be asked to complete a simple symptom scale by making a mark on a line to show how much breathlessness and how much chest pain (if any) they are experiencing.

Patients will be randomly allocated to receive local anaesthetic thoracoscopy with talc and IPC insertion (intervention arm) or local anaesthetic thoracoscopy with talc alone (standard care arm).

Patients receiving an IPC in the intervention arm will be assessed by their treating clinician to determine whether they can be discharged home the same day after their trial procedure. Patients allocated to the standard care arm will require hospital admission after their trial procedure. They will be assessed on a daily basis to determine suitability for discharge home.

Patients receiving an IPC will have the tube drained daily (minimum 5 days per week) for the first 14 days by nurses at local sites if a hospital inpatient or district nurses once the patient is home.

All patients will have a diary to take home. They will be asked to record breathlessness and chest pain levels on a symptom scale twice per week for 4 weeks. They will also be asked to record any contact they have with healthcare providers.

Patients with an IPC in place will have space to record the amount of fluid drained at each nurse visit in the patient diary. They will be advised to contact their local trial team if the amount drained is less than 50 ml on three occasions, for an assessment to consider whether the fluid has dried up and the IPC may be removed.

After hospital discharge, patients will be seen in clinic at 2 weeks, 4 weeks and 12 weeks following their procedure. At these appointments they will be asked about symptoms, quality of life and will be asked to have a chest ultrasound and chest x-ray. If COVID-19 risk is judged at the time to outweigh the requirement for face-to-face review, appointments at 12 weeks post-procedure may be conducted by phone or video consultation.

Patients consenting to take part in the interview will be contacted to confirm a convenient date and time. Interviews will take place between 4 and 12 weeks (+/- 1 week) after the trial procedure and will be conducted by phone or computer-based video call by an experienced qualitative researcher.

The trial will recruit in an 'open label' manner, which means both the patient and trial team are aware of the allocated treatment arm. It is not possible to blind because the patients in the intervention arm will receive indwelling pleural catheters (which are visible tubes inserted on the chest) whereas patients in the standard care arm will not. It is not considered safe or ethical to undertake 'dummy' procedures.

To minimise bias, suggested hospital discharge criteria are recommended and will be applied equally to patients in both arms of the trial. Where follow up chest x-rays or ultrasound scans show recurrence of at least a moderate-sized pleural effusion and where local doctors choose not to intervene with a repeat procedure to drain away the fluid, a discussion will be had with a blinded clinician in one of the key trial centres (Oxford or Bristol) to justify the decision. All patients judged to have a 'pleurodesis failure' during the trial (reaccumulation of fluid following drainage) will have chest x-rays taken at 4 and 12 weeks reviewed by independent observers.

Intervention Type
Procedure/Surgery

Primary outcome measure
The co-primary outcomes are:
1. Total number of days spent in hospital (including re-admissions) captured from patient diaries and medical records over 4 weeks post-procedure
2. Breathlessness score over 4 weeks post-procedure measured using a 100 mm visual analogue score (VAS) at baseline and then twice weekly for 4 weeks

Secondary outcome measures
1. Mean chest pain score over 4 weeks post-procedure measured using a 100 mm visual analogue score (VAS) at baseline then twice weekly for 4 weeks
2. Total number of days spent in hospital captured from patient diaries and medical records over

12 weeks post-procedure
3. Total number of days until medically appropriate for discharge from hospital over 4 and 12 weeks post-procedure according to discharge criteria specified in the protocol and trial-specific procedures
4. Number of patients with successful pleurodesis, defined as absence of pleural effusion of at least moderate size defined radiologically (greater than or equal to 1/3rd of hemithorax on CXR, or >2 rib spaces and 4 cm depth on ultrasound) AND a. Lack of clinical need for further pleural procedure as judged by local investigator* OR b. For IPC patients, fluid output of <50 ml on three consecutive drainages. Measured at 4 and 12 weeks post-procedure
5. Number of contacts with healthcare professionals concerning malignant pleural effusion management, captured from patient diaries and medical records at 12 weeks post-discharge from hospital following the initial procedure
6. Quality of life measured using EQ5D-5L and EORTC QLQc30 at baseline, 4 and 12 weeks post-procedure
7. Healthcare costs and cost-effectiveness of the interventions:
7.1. Costs incurred over 12 weeks from the NHS perspective: drains (IPC and large bore drain), further thoracoscopic talc pleurodesis (TTP) interventions, inpatient, outpatient, emergency, primary care visits
7.2. Cost-effectiveness: within-trial cost-utility analysis to explore incremental cost per QALY gained of TTP+IPC compared to TTP alone
Measured at 4 and 12 weeks post-procedure
8. Caregiver burden during post-procedure care assessed using SF-36, GHQ12, WPAI(CG) questionnaires and a five-item caregiving scale at baseline, 4 and 12 weeks after the patients trial procedure (optional aspect of trial for patients primary caregiver)
9. Experience and impact on patients and their primary carers assessed using a semi-structured interview between 4 and 12 weeks post-trial procedure (optional aspect of trial)

Overall study start date
21/03/2018

Completion date
30/04/2024

Eligibility

Key inclusion criteria
1. Symptomatic pleural effusion and any of the following:
1.1. Thoracoscopically confirmed evidence of malignant pleural disease (visible cancer at thoracoscopy) which requires talc poudrage as part of routine clinical care
1.2. An established diagnosis of malignant pleural effusion (via biopsy or cytology) which requires drainage and pleurodesis as per standard care, where the patient/operator decide on a thoracoscopic treatment
1.3. Symptomatic effusion requiring drainage and pleurodesis in the context of established metastatic disease
2. Able to consent to trial inclusion

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 124; UK Sample Size: 124

Total final enrolment
124

Key exclusion criteria
1. Technically unable to undergo thoracoscopy and talc poudrage (e.g. gross respiratory failure, uncorrectable clotting, unable to tolerate position, significant suspicion of underlying trapped lung or poor performance status)
2. Visual impairment (precluding use of symptom measurement instruments)
3. Previous talc pleurodesis within the last 3 months on ipsilateral side
4. No means of phone contact
5. Age <18 years
6. Females who are pregnant or lactating
7. Unable to consent to trial inclusion

Date of first enrolment
01/11/2021

Date of final enrolment
03/01/2024

Locations

Countries of recruitment
England

Scotland

United Kingdom

Wales

Study participating centre
Southmead Hospital
North Bristol NHS Trust
Bristol
United Kingdom
BS10 5NB

Study participating centre
Churchill Hospital
Oxford University Hospitals NHS Foundation Trust
Oxford
United Kingdom
OX3 7LE

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

Study participating centre
Derriford Hospital
University Hospitals Plymouth NHS Trust
Plymouth
United Kingdom
PL6 8DH

Study participating centre
Glenfield Hospital
University Hospitals of Leicester NHS Trust
Leicester
United Kingdom
LE3 9QP

Study participating centre
Glan Clwyd Hospital
Betsi Cadwaladr University Health Board
Rhyl
United Kingdom
LL18 5UJ

Study participating centre
Royal Stoke University Hospital
University Hospitals of North Midlands NHS Trust

Stoke-on-Trent
United Kingdom
ST4 6QG

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

Study participating centre
Wythenshawe Hospital
Manchester University NHS Foundation Trust
Manchester
United Kingdom
M23 9LT

Study participating centre
Macclesfield District General Hospital
East Cheshire NHS Trust
Macclesfield
United Kingdom
SK10 3BL

Study participating centre
Northern General Hospital
Northern General Hospital NHS Trust
C Floor, Huntsman Building
Herries Road
Sheffield
United Kingdom
S5 7AU

Sponsor information

Organisation
North Bristol NHS Trust

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+44 (0)1174149333
ResearchSponsor@nbt.nhs.uk

Sponsor type
Hospital/treatment centre

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

ROR
https://ror.org/036x6gt55

Funder(s)

Funder type
Government

Funder Name
NIHR Central Commissioning Facility (CCF); Grant Codes: PB-PG-1217-20037

Results and Publications

Publication and dissemination plan
The researchers will publish the protocol separately. The trial results will be published in a peer-reviewed journal and presented at national and international conferences.

Intention to publish date
14/01/2025

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?
Protocol article	protocol	30/05/2023	31/05/2023	Yes	No
HRA research summary			28/06/2023	No	No
Basic results			07/07/2025	No	No