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A randomised trial to determine the best method for delivering talc for the management of malignant pleural effusions in patients with a good performance status

Submission date
24/05/2012

Recruitment status
No longer recruiting

Registration date
28/05/2012

Overall study status
Completed

Last Edited
06/12/2019

Condition category
Cancer

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

Plain English summary of protocol
http://www.cancerresearchuk.org/cancer-help/trials/a-trial-looking-at-how-treat-fluid-lung-tapps

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
HTA 10/50/42, 2843, UKCRN:12537

Study information

Scientific Title
Evaluating the efficacy of Thoracoscopy And talc Poudrage versus Pleurodesis using talc Slurry: A randomised, open-label trial to determine the most effective method for the management of malignant pleural effusions in patients with a good performance status

Acronym
TAPPS

Study objectives
Primary research question:
Does thoracoscopy and talc poudrage increase the proportion of patients with successful pleurodesis at three months post-procedure, when compared to standard therapy with chest drain insertion and talc slurry instillation?

Secondary research questions:
1. Does thoracoscopy and talc poudrage reduce the time to pleurodesis failure, measured at three and six months post-procedure, when compared to standard therapy with chest drain insertion and talc slurry instillation?
2. Does fluid drainage and talc poudrage at thoracoscopy improve chest x-ray appearances at 24 hours and at 3 months post-procedure, when compared to standard fluid drainage via chest tube alone?
3. Does thoracoscopy and talc poudrage cause less breathlessness and thoracic pain for the first five days post-procedure, when compared to standard therapy with chest drain insertion and talc slurry instillation?
4. Does thoracoscopy and talc poudrage improve health-related quality of life over the six months post-procedure, when compared to standard therapy with chest drain insertion and talc slurry instillation?
5. Is thoracoscopy and talc poudrage cost effective over six months, when compared to standard therapy with chest drain insertion and talc slurry instillation?
6. Does thoracoscopy and talc poudrage reduce healthcare utilisation during the six months post-procedure, when compared to standard therapy with chest drain insertion and talc slurry instillation?

On 07/01/2015 the overall trial end date was changed from 15/01/2015 to 31/01/2017.

Ethics approval required
Old ethics approval format

Ethics approval(s)
NRES Committee North West – Preston, 26/06/2012, ref: 12/NW/0467

Primary study design
Interventional

Study design
Randomised open-label multi-centre trial

Study type(s)
Treatment

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

Interventions
1. Small-bore chest drain insertion followed by 4 g graded sterile talc slurry pleurodesis
2. Medical (local anaesthetic) thoracoscopy followed by 4 g graded sterile talc poudrage

Intervention Type
Procedure/Surgery

Primary outcome(s)
Number of patients who experience pleurodesis failure up to three months (90 days) post randomisation

Key secondary outcome(s)
1. Requirement for further pleural procedures up to 6 months post-randomisation, as assessed by two independent, blinded adjudicators. The adjudicator will be provided with relevant radiological images and information regarding the patient's health status, including performance status and Visual Analogue Scores (VAS) scores for breathlessness and thoracic pain
2. Percentage radiographic (chest x-ray) pleural opacification, measured by visual estimation in a blinded fashion, on the side of the pleurodesis attempt at 24 hours post poudrage or slurry instillation, and at 3 and 6 months post randomisation
3. Self-reported health-related quality of life, as measured using the SF-36 and EQ-5D questionnaires measured at 1 month, 3 months and 6 months post randomisation
4. Self-reported thoracic pain, as measured using VAS scores recorded daily for the first 7 days post randomisation, and then weekly for the duration of trial follow-up
5. Self-reported breathlessness, as measured using VAS scores recorded daily for the first 7 days post randomisation, and then weekly for the duration of trial follow-up.
6. The number of patients with pleurodesis failure up to one month (30 days) post randomisation
7. The number of patients with pleurodesis failure up to six months (180 days) post randomisation
8. All-cause mortality up to six months (180 days) post-randomisation
9. Time to pleurodesis failure, censored at six months (180 days) post randomisation
10. Time from randomisation to hospital discharge
11. Number of days spent as a hospital inpatient up to three months
12. Healthcare resource usage and costs at six months (180 days) post randomisation
13. The costs of performing talc pleurodesis under the two interventions under study
14. Follow-up costs

Completion date
31/10/2018

Eligibility

Key inclusion criteria
1. Clinically confident diagnosis of malignant pleural effusion requiring pleurodesis, defined as:
1.1. Pleural effusion with histocytologically proven pleural malignancy OR
1.2. Pleural effusion in the context of histocytologically proven malignancy elsewhere, without a clear alternative cause for fluid OR
1.3. Pleural effusion with typical features of malignancy with pleural involvement on cross-sectional imaging (CT/MRI)
2. Fit enough to undergo local anaesthetic thoracoscopy, as per British Thoracic Society (BTS) guidelines
3. Expected survival >3 months
4. Written, informed consent to trial participation

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Total final enrolment
330

Key exclusion criteria
1. Patients in whom thoracoscopy is the only reasonable approach to making a diagnosis, and in whom such a diagnosis would significantly influence further management
2. Age < 18 years
3. Females who are pregnant or lactating
4. Evidence of extensive lung entrapment on chest X-ray (CXR) or CT, or significant fluid loculation on ultrasound scan, to a level which would normally be a contraindication to attempted talc pleurodesis
5. Insufficient volume or position of pleural fluid on lateral decubitus thoracic ultrasound to safely perform local anaesthetic thoracoscopy without further intervention being necessary
6. Previously documented adverse reaction to talc
7. Clear contraindication to thoracoscopy or chest tube insertion

Date of first enrolment
01/08/2012

Date of final enrolment
24/10/2017

Locations

Countries of recruitment
United Kingdom

England

Scotland

Study participating centre
Southmead Hospital
Monks Park Avenue
Bristol
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Study participating centre
Nottingham City Hospital
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Study participating centre
Musgrove Park Hospital
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TA1 5DA

Study participating centre
Churchill Hospital
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Lancashire Teaching Hospitals NHS Foundation Trust
Fulwood
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PR2 9HT

Study participating centre
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Study participating centre
Addenbrooke's Hospital
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CB2 0QQ

Study participating centre
St Thomas' Hospital
Westminster Bridge Road
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Study participating centre

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Armthorpe Road
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TS19 8PE

Study participating centre
Aintree University Hospital
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Study participating centre
Southern General Hospital
1345 Govan Road
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G51 4TF

Study participating centre
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Study participating centre
Queen Elizabeth Hospital
Birmingham
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B15 2TH

Sponsor information

Organisation
North Bristol NHS Trust (UK)

ROR
https://ror.org/036x6gt55

Funder(s)

Funder type
Government

Funder Name
NIHR Health Technology Assessment (HTA) (UK) (ref. 10/50/42)

Results and Publications

Individual participant data (IPD) sharing plan
The trial was funded by the NIHR HTA programme, who will publish the full data and a comprehensive study report at the same time as the academic manuscript. This will be open access and thus available to anyone in perpetuity. For further information email the study Chief Investigator, Nick Maskell, at nick.maskell@bristol.ac.uk. Consent was obtained and all data are anonymised.

IPD sharing plan summary
Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	05/12/2019	06/12/2019	Yes	No
Protocol article	protocol	26/11/2014		Yes	No
Other publications	strategies	21/11/2014		Yes	No