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	Recruitment status No longer recruiting	[X] Prospectively registered		
24/05/2012		[X] Protocol		
Registration date 28/05/2012	Overall study status Completed	Statistical analysis plan		
		[X] Results		
Last Edited	Condition category	[] Individual participant data		
06/12/2019	Cancer			

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

Contact name

Dr Nick Maskell

Contact details

Respiratory Research Unit Southmead Hospital Bristol United Kingdom BS10 5NB

nick.maskell@nbt.nhs.uk

Type(s)

Scientific

Contact name

Dr Rahul Bhatnagar

Contact details

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United Kingdom

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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

Study design

Randomised open-label multi-centre trial

Primary study design

Interventional

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 United Kingdom BS10 5NB

Study participating centre Nottingham City Hospital

Hucknall Road Nottingham United Kingdom NG5 1PB

Study participating centre Musgrove Park Hospital

Taunton United Kingdom TA1 5DA

Study participating centre Churchill Hospital

Headington Oxford United Kingdom OX3 7LE

Study participating centre Medway Maritime Hospital

Gillingham United Kingdom ME7 5NY

Study participating centre King's Mill Hospital

Mansfield Road Sutton in Ashfield Nottingham United Kingdom NG17 4JL

Study participating centre Lancashire Teaching Hospitals NHS Foundation Trust

Fulwood Preston United Kingdom PR2 9HT

Study participating centre Wythenshawe Hospital

Southmoor Road Wythenshawe Manchester United Kingdom M23 9LT

Study participating centre Addenbrooke's Hospital

Hills Road Cambridge United Kingdom CB2 0QQ

Study participating centre St Thomas' Hospital

Westminster Bridge Road London United Kingdom SE1 7EH

Study participating centre

Doncaster Royal Infirmary

Armthorpe Road Doncaster United Kingdom DN2 5LT

Study participating centre University Hospital of North Tees

Hardwick Stockton United Kingdom TS19 8PE

Study participating centre Aintree University Hospital

Liverpool United Kingdom L9 7AL

Study participating centre Southern General Hospital

1345 Govan Road Glasgow United Kingdom G51 4TF

Study participating centre Milton Keynes Hospital NHS Foundation Trust

Standing Way Eaglestone Milton Keynes United Kingdom MK6 5LD

Study participating centre Queen Elizabeth Hospital

Birmingham United Kingdom 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 results	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		05/12/2019	06/12/2019	Yes	No
Protocol article	protocol	26/11/2014		Yes	No
Other publications	strategies	21/11/2014		Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes