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The first Therapeutic Interventions in Malignant Effusion trial

Submission date 11/03/2006	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 19/04/2006	**Overall study status** Completed	
Last Edited 31/03/2022	**Condition category** Cancer	

Plain English summary of protocol
https://www.cancerresearchuk.org/about-cancer/find-a-clinical-trial/a-trial-to-find-the-best-way-of-controlling-pain-during-and-after-pleurodesis

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
2005-005226-31

IRAS number

ClinicalTrials.gov number
NCT00644319

Secondary identifying numbers

1.1

Study information

Scientific Title
The first Therapeutic Interventions in Malignant Effusion trial

Acronym
TIME1

Study objectives
The TIME1 study is a 2 x 2 randomised factorial trial to assess whether non-steroidal (ibuprofen) analgesia and the use of small bore chest tubes will reduce pain during pleurodesis for malignant effusion, compared to standard care. The trial will also define whether non-steroidal use decreases pleurodesis efficacy.

Ethics approval required
Old ethics approval format

Ethics approval(s)
West Essex Local Research Ethics Committee, 24/04/2006, ref: 05/Q0301/61

Study design
2 x 2 randomised factorial 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 below to request a patient information sheet

Health condition(s) or problem(s) studied
Malignant pleural effusion, including mesothelioma

Interventions
Participants will undergo normal care (thoracoscopy and talc poudrage or talc slurry pleurodesis via drain), using standardised pre-procedure sedation and analgesia as per protocol. The sizes of chest tubes to be used are predefined (large [24F] and small [12F]). The analgesic regimens are:
1. NSAID: ibuprofen 800 mg three times daily (tds) to a maximum of 8-hourly
2. Opiate: diamorphine 2.5 mg, intravenous (IV) administration, four times daily (qds) to a

maximum of 10 mg
3. Rescue: patients will always have access to rescue analgesia as required (diamorphine 2.5 mg IV)
Treatment continues from pleurodesis (day 0) to tube removal (day 3).

Participants will be randomised to one of the following arms:
1. Large bore (24F) chest drain and NSAID-based analgesic regimen
2. Small bore (12F) chest drain and NSAID-based analgesic regimen
3. Large bore chest drain (24F) and opiate-based analgesic regimen
4. Small bore chest drain (12F) and opiate-based analgesic regimen

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Ibuprofen

Primary outcome measure
Pain score over 72 hours post pleurodesis for malignant pleural effusion, taken by administering 100 mm visual analogue pain score (VAS), to calculate the total pain relief (TOTPAR) score, over 3 days

Secondary outcome measures
1. Success of pleurodesis at six weeks and three months post randomisation (time to relapse of pleural effusion, survival analysis)
2. Presence of chronic chest pain on the side of the pleurodesis at six weeks and three months post randomisation

Overall study start date
26/03/2007

Completion date
31/12/2009

Eligibility

Key inclusion criteria
1. Clinically confident diagnosis of malignant pleural effusion requiring pleurodesis
Definitions:
1.1. Histologically proven pleural malignancy
1.2. Typical features of pleural malignancy seen on direct vision during thoracoscopy
1.3. Pleural effusion in the context of histologically proven cancer elsewhere
2. Written informed consent
3. Expected survival more than one month

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
320 (interim analysis after 120 patients)

Total final enrolment
320

Key exclusion criteria
1. Age less than 18 years
2. Primary lymphoma or small cell lung carcinoma
3. Patients who are pregnant or lactating
4. Inability to give informed consent
5. History of gastrointestinal (GI) bleeding or of untreated peptic ulceration
6. Known sensitivity to non-steroidal anti-inflammatory drugs (NSAIDs) or opiates
7. Hypercapnic ventilatory failure
8. Known intravenous drug abuse
9. Severe renal or liver disease
10. Known bleeding diathesis
11. Warfarin therapy which must be continued
12. Current or recent (within two weeks) corticosteroid steroid therapy

Date of first enrolment
26/03/2007

Date of final enrolment
31/12/2009

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Oxford Centre for Respiratory Medicine
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Sponsor information

Organisation
University of Oxford (UK)

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Sponsor type
University/education

ROR
https://ror.org/052gg0110

Funder(s)

Funder type
University/education

Funder Name
University of Oxford (UK)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan
Not provided at time of registration

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?

Results article	results	01/12/2015		Yes	No
Plain English results			31/03/2022	No	Yes