ISRCTN34841555 https://doi.org/10.1186/ISRCTN34841555

A randomised study of the value of acupuncture in treating non small cell lung cancer and mesothelioma patients with dyspnoea

Submission date
09/02/2006

Recruitment status
No longer recruiting

Registration date
23/02/2006

Overall study status
Completed

Last Edited
23/03/2018

Condition category
Cancer

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

Plain English summary of protocol

Background and study aims
Non-small cell lung cancer (NSCLC) is the most common type of lung cancer, making up around 85-90% of all cases. As the health of the lungs deteriorates, many patients experience breathlessness, as their lungs are no longer able to function properly. This can be painful and distressing to sufferers, as constant breathlessness, even while at rest, can prevent them from taking part in many activities. Currently, the only medical treatment offered for these patients is morphine (a powerful pain-relieving drug), although this is not thought to help particularly and has many unwanted side-effects. Acupuncture is a popular treatment taken from ancient Chinese medicine, in which fine needels are placed into the body at specific points. Studies have shown that it can help to stimulate nerves under the skin, causing the body to produce natural pain-relieving substances (endorphins). There is evidence that it is effective in a range of conditions, including problems with breathing. The aim of this study is to find out whether acupuncture treatment can help to relieve breathlessness in patients suffering from NSCLC.

Who can participate?
Adult patients with non-small cell lung cancer (NSCLC) who experience breathlessness at rest.

What does the study involve?
Participants are randomly allocated to one of three groups. Those in the first group are given morphine for pain relief only. Those in the second group are given acupuncture treatment. This involves an initial session of acupuncture, where thin needles are placed in the skin in specific places, followed by the semi-permanent acupuncture studs being placed into the skin that are to be left in place for 14 days. Those in the third group are given morphine as well as acupuncture treatment in the same way as the second group. All participants attend study visits at the start of the study and then after 7 and 14 days to complete a physical assessment to measure breathlessness and a number of questionnaires to assess their mood and wellbeing.

What are the possible benefits and risks of participating?
Not provided at time of registration

Where is the study run from?
Royal Marsden Hospital (UK)

When is the study starting and how long is it expected to run for?
May 2006 to January 2014

Who is funding the study?
Royal Marsden Hospital (UK)

Who is the main contact?
Dr Mary O'Brien

Contact information

Type(s)
Scientific

Contact name
Dr Mary O'Brien

Contact details
Royal Marsden Hospital
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Sutton
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Additional identifiers

Protocol serial number
N/A

Study information

Scientific Title
A randomised study of the value of acupuncture in treating non small cell lung cancer and mesothelioma patients with dyspnoea

Study objectives
Some studies on breathlessness, while small, have shown acupuncture to have a significant positive effect in the perception of breathlessness in end-stage cancer, chronic obstructive pulmonary disease and asthma. The vast majority of trials of acupuncture for breathlessness have been performed in a non-cancer setting. Therefore, the lack of data regarding effectiveness of acupuncture and standard opioids for cancer-related dyspnoea, together with drawbacks associated with opioid use and service acupuncture in the National Health Service (NHS) for this indication, warrant further research.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Royal Marsden Research Ethics Committee, May 2006

Study design
Randomised phase II trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Non-small cell lung cancer and mesothelioma

Interventions
Patients are randomised to receive one of the following interventions:
1. Morphine
2. Acupuncture
3. Morphine and acupuncture

After completing baseline assessments patients will undergo treatment on day one according to which treatment arm they have been randomized to. Those in treatment arms two and three will have indwelling acupuncture studs inserted after their initial acupuncture treatment. During the course of day 1 all patients will undergo further assessments after their initial treatment. All patients will return for assessment on days 7 and 14 (this last visit marks the end of trial). Those patients who feel a beneficial effect of the acupuncture studs will be allowed to retain them and followed up in the usual outpatient clinic.

Intervention Type
Mixed

Primary outcome(s)
The effectiveness of acupuncture for relief of breathlessness in lung cancer

Key secondary outcome(s))
1. Measures of anxiety, relaxation, other subjective variables (Lar scales)
2. Respiratory rate and lung function tests (Forced Expiratory Volume [FEV], Partial Expiratory Flow Rate [PEFR])
3. Hospital Anxiety and Depression (HAD) Scale
4. Quality of Life (QOL) changes between baseline and 7 days

Completion date
31/01/2014

Eligibility

Key inclusion criteria

Patients with a diagnosis of Non Small Cell Lung Cancer (NSCLC) and mesothelioma and breathless at rest with at least a Visual Analogue Scale (VAS) score >/= 4, or breathlessness at rest

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
1. Recent acupuncture in the last four weeks
2. Contraindications to acupuncture e.g bleeding abnormality or anticoagulation
3. Current use of morphine in any form (oral or nebuliser) at study entry
4. Untreated reversible anaemia, pleural effusion, pulmonary embolism, pneumonia, ascites, or superior vena cava obstruction, if treatment appropriate
5. Pregnancy
6. Commenced oral or inhaled steroids or changed dose within one week of the start of the study
7. Chemotherapy or radiotherapy or change in hormonotherapy in the last four weeks

Date of first enrolment
01/05/2006

Date of final enrolment
31/01/2014

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Royal Marsden Hospital
Sutton
United Kingdom
SM2 5PT

Sponsor information

Organisation
Royal Marsden Hospital (UK)

ROR
https://ror.org/034vb5t35

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Royal Marsden Hospital (UK)

Results and Publications

Individual participant data (IPD) sharing plan

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	01/07/2016		Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes