

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

<b>Submission date</b> 09/02/2006	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 23/02/2006	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 23/03/2018	<b>Condition category</b> Cancer	<input type="checkbox"/> 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 needles 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  
Downs road  
Sutton  
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## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**  
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

**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 patient information sheet

**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 measure**

The effectiveness of acupuncture for relief of breathlessness in lung cancer

## Secondary outcome measures

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

## Overall study start date

01/05/2006

## 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  $\geq 4$ , or breathlessness at rest

## Participant type(s)

Patient

## Age group

Adult

## Sex

Both

## Target number of participants

174

## 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**

England

United Kingdom

**Study participating centre**

**Royal Marsden Hospital**

Sutton

United Kingdom

SM2 5PT

## **Sponsor information**

**Organisation**

Royal Marsden Hospital (UK)

**Sponsor details**

Downs road

Sutton

England

United Kingdom

SM2 5PT

**Sponsor type**

Hospital/treatment centre

**Website**

<http://www.royalmarsden.org>

**ROR**

<https://ror.org/034vb5t35>

## **Funder(s)**

**Funder type**

Hospital/treatment centre

**Funder Name**

Royal Marsden Hospital (UK)

# Results and Publications

## Publication and dissemination plan

Not provided at time of registration

## Intention to publish date

## 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?
<a href="#">Results article</a>	results	01/07/2016		Yes	No