

# CALC trial: Aprepitant for the treatment of cough in lung cancer

<b>Submission date</b> 26/03/2013	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 26/03/2013	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 24/09/2020	<b>Condition category</b> Cancer	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

<http://www.cancerresearchuk.org/cancer-help/trials/a-trial-looking-at-aprepitant-to-treat-cough-in-people-with-lung-cancer-calc>

## Contact information

### Type(s)

Scientific

### Contact name

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### Contact details

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## Additional identifiers

### Protocol serial number

13989

## Study information

### Scientific Title

A single-arm double-blind placebo-controlled cross-over trial of Aprepitant for the treatment of cough in lung cancer: CALC trial

**Acronym**

CALC

**Study objectives**

A single-arm placebo controlled crossover study of Aprepitant for the treatment of cough in lung cancer.

Aprepitant is an effective antitussive for patients with lung cancer.

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

NRES Committee North West Liverpool East, 22/03/2013, ref: 13/NW/0084

**Study design**

Randomised single-arm placebo-controlled crossover study

**Primary study design**

Interventional

**Study type(s)**

Treatment

**Health condition(s) or problem(s) studied**

Topic: National Cancer Research Network; Subtopic: Lung Cancer; Disease: Lung (small cell), Lung (non-small cell)

**Interventions**

Patients will receive 3 days treatment with aprepitant/placebo at standard doses: 125mg D1, 80mg D2 and 80mg D3 followed by 3 days washout period and 3 further days of aprepitant /placebo at standard doses.

**Intervention Type**

Drug

**Phase**

Not Applicable

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

Aprepitant

**Primary outcome(s)**

Daytime ambulatory cough monitoring; Timepoint(s): Baseline, D3 and D9

**Key secondary outcome(s)**

1. Biomarker Analysis; Timepoint(s): Day 3 and Day 9
2. Cough Severity Visual Analogue Scale score; Timepoint(s): Baseline, Day 3 and Day 9
3. Manchester Cough in Lung Cancer Scale score; Timepoint(s): Baseline, Day 3 and Day 9

**Completion date**

31/03/2014

## Eligibility

**Key inclusion criteria**

1. Patients willing and able to give consent for participation in the trial
2. Male or female aged 18 years or above
3. WHO PS 02
4. Diagnosed with lung cancer
5. Able and willing to participate in and comply with the trial schedule
6. Persistent cough  $\geq$  4 weeks
7. Not on anticancer therapy
8. No anticancer therapy planned to commence for the duration of the trial participation

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

18 years

**Sex**

All

**Total final enrolment**

20

**Key exclusion criteria**

1. Received anticancer therapy within 4 weeks of trial entry
2. Receiving Aprepitant therapy
3. Presence of a RTI within last 4 weeks
4. Previous adverse event to Aprepitant
5. Presence of constipation grade 2 or above (CTCAE v4)
6. Scheduled elective surgery or other procedures requiring sedation or general anaesthesia during trial period
7. Potentially fertile women of childbearing age
8. Currently participating in another research trial involving an investigational product
9. Any other significant disease or disorder which, in the opinion of the investigator, may either put the patient at risk because of participation in the trial or affect the patients ability to participate in the trial

**Date of first enrolment**

01/04/2013

**Date of final enrolment**

31/03/2014

## Locations

**Countries of recruitment**

United Kingdom

England

**Study participating centre**

Christie Hospital NHS Foundation Trust

Manchester

United Kingdom

M20 4BX

## Sponsor information

**Organisation**

Christie Hospital NHS Foundation Trust (UK)

**ROR**

<https://ror.org/03v9efr22>

## Funder(s)

**Funder type**

Government

**Funder Name**

National Institute for Health Research (NIHR) (UK)

**Alternative Name(s)**

National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

**Funding Body Type**

Government organisation

**Funding Body Subtype**

National government

## Location

United Kingdom

## Funder Name

North West Lung Centre Charity (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?
<a href="#">Results article</a>	results	10/10/2015		Yes	No
<a href="#">Results article</a>	results	15/03/2021	24/09/2020	Yes	No
<a href="#">HRA research summary</a>			28/06/2023	No	No
<a href="#">Plain English results</a>				No	Yes