

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

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

Primary study design

Interventional

Study design

Randomised single-arm placebo-controlled crossover study

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?
Results article	results	10/10/2015		Yes	No
Results article	results	15/03/2021	24/09/2020	Yes	No
HRA research summary			28/06/2023	No	No
Plain English results				No	Yes