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

Submission date	Recruitment status	[X] Prospectively registered
26/03/2013	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
26/03/2013	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
24/09/2020	Cancer	

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

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised cross over trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet

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

Secondary outcome measures
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

Overall study start date
01/04/2013

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 >= 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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 20; UK Sample Size: 20

Total final enrolment

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
England

United Kingdom

Study participating centre
Christie Hospital NHS Foundation Trust
Manchester
United Kingdom
M20 4BX

Sponsor information

Organisation
Christie Hospital NHS Foundation Trust (UK)

Sponsor details
550 Wilmslow Road
Manchester
England
United Kingdom
M20 4BX

Sponsor type
Hospital/treatment centre

Website
http://www.christie.nhs.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

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?
Plain English results				No	Yes
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