

Efficacy and safety of cineole in patients with acute bronchitis with productive cough

Submission date 02/02/2010	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 24/02/2010	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 25/11/2013	Condition category Respiratory	☐ Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
2008-006061-86

Protocol serial number
K/604

Study information

Scientific Title
Multicentre, randomised, double-blind, placebo-controlled parallel group comparison in order to prove efficacy and safety of Cineole in patients with acute bronchitis with productive cough

Study objectives

Change of bronchitis-sum-score will improve more in the cineole group

Ethics approval required

Old ethics approval format

Ethics approval(s)

Lower Saxony (Niedersachsen) Medical Association Ethics Committee approved on the 23/12/2009 (ref: 15/2009)

Primary study design

Interventional

Study design

Multicentre randomised double blind placebo controlled parallel group trial

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Acute bronchitis with productive cough

Interventions

Patients will be randomised to receive either:

1. Cineole
2. Placebo

One capsule with 200 mg or without active ingredient will be given three times daily over a period of 10 days. The capsules are organoleptically identical.

The follow-up period will be four days.

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Cineole

Primary outcome(s)

Bronchitis-sum-score, including the most relevant parameters:

1. Intensity of dyspnoea
2. Sputum quantity
3. Number of daily cough attacks
4. Pain at cough
5. Auscultation
6. Spirometry

Outcomes will be measured at baseline and after 4 and 10 days of treatment.

Key secondary outcome(s)

Single parameters of bronchitis-sum-score

Outcomes will be measured at baseline and after 4 and 10 days of treatment.

Completion date

30/04/2011

Eligibility

Key inclusion criteria

Patients with acute bronchitis with productive cough, a bronchitis sum-score > 7

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Key exclusion criteria

1. Age < 18 and > 70 years
2. Comedication with other mucolytics

Date of first enrolment

05/02/2010

Date of final enrolment

30/04/2011

Locations

Countries of recruitment

Germany

Study participating centre

Klinik Norderney

Norderney

Germany

26548

Sponsor information

Organisation

MKL Institute of Clinical Research (MKL Institut für Klinische Forschung GmbH) (Germany)

Funder(s)**Funder type**

Industry

Funder Name

Cassella-med GmbH (Germany) - research grant

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	21/11/2013		Yes	No