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

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
2008-006061-86

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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)

Study design
Multicentre randomised double blind placebo controlled parallel group 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 contact details below to request a patient information sheet (in German)

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 measure
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.

Secondary outcome measures
Single parameters of bronchitis-sum-score
Outcomes will be measured at baseline and after 4 and 10 days of treatment.

Overall study start date
05/02/2010

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

Age group
Adult

Sex
Both

Target number of participants
240

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)

Sponsor details
c/o Dr. Uwe Dethlefsen
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Aachen
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Sponsor type
Industry

Funder(s)

Funder type
Industry

Funder Name
Cassella-med GmbH (Germany) - research grant

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?
Results article	results	21/11/2013		Yes	No