ISRCTN07600011 https://doi.org/10.1186/ISRCTN07600011

Multicentre, randomised, double-blind, placebo-controlled, parallel-group comparison in order to prove efficacy and tolerability of cineole in the long-term treatment of patients with chronic obstructive pulmonary disease (COPD)

Submission date
15/10/2008

Recruitment status
No longer recruiting

Registration date
27/10/2008

Overall study status
Completed

Last Edited
30/07/2009

Condition category
Respiratory

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
K/588

Study information

Scientific Title

Study objectives
Concomitant cineole therapy in addition to basic treatment will reduce exacerbations in patients with chronic obstructive pulmonary disease (COPD).

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Ethics Committee of Bayerische Landesaerztekammer, Muenchen, approved on 11th September 2003
2. Medical Association Nordrhein, Duesseldorf, approved on 11th November 2003
3. Medical Association Westfalen-Lippen, Muenster, approved on 18th September 2003
4. Medical Association Hessen, Frankfurtf, approved on 2nd October 2003
5. Medical Association Hamburg, approved on 12th September 2003
6. Ethics Committee of Saechsiche Landesaertekammer, Dresden, approved on 15th December 2003

Study design
Multicentre randomised double-blind placebo-controlled parallel-group trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Chronic obstructive pulmonary disease (COPD)

Interventions
Cineole 200 mg (oral) three times per day in addition to basic treatment, for 6 months during winter. Control group received placebo capsules.

Intervention Type
Drug

Phase
Not Specified

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

Primary outcome measure
Difference between exacerbations (number, time, sevrity).

The primary and secondary outcomes were assessed at initial visit and after 1, 2 ,3, 4, 5 and 6 months of treatment.

Secondary outcome measures
1. Symptoms of COPD (dyspnoea, secretion, cough)
2. Spirometry: FEV1, forced vital capacity (FVC), vital capacity (VC)
3. Quality of life, assessed by the St George's Respiratory Questionnaire (SGRQ)

The primary and secondary outcomes were assessed at initial visit and after 1, 2 ,3, 4, 5 and 6 months of treatment.

Overall study start date
26/09/2003

Completion date
06/07/2005

Eligibility

Key inclusion criteria
1. Patients (both males and females) with COPD, at least three exacerbations during the winter months
2. Forced expiratory volume in 1 second (FEV1) greater than 30% and less than 70% of predicted value, increase of FEV1 less than 15% and less than 200 ml after inhalation of beta-agonists
3. Smoker/ex-smoker greater than 10 pack years

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
240

Key exclusion criteria
1. Aged less than 40 years and greater than 80 years
2. Asthma bronchiale
3. Comedication with other mucolytics
4. Infection at the beginning of the study

Date of first enrolment
26/09/2003

Date of final enrolment
06/07/2005

Locations

Countries of recruitment
Germany

Study participating centre
Medizinische Klinik I
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90766

Sponsor information

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

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Sponsor type
Industry

Funder(s)

Funder type

Industry

Funder Name
Cassella-med GmbH & Co. KG. (Germany)

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	22/07/2009		Yes	No