

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	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 27/10/2008	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 30/07/2009	Condition category Respiratory	<input type="checkbox"/> 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

Protocol serial number
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 Landesärztekammer, 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 Saechsische Landesärztekammer, Dresden, approved on 15th December 2003

Study design

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

Primary study design

Interventional

Study type(s)

Treatment

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(s)

Difference between exacerbations (number, time, severity).

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

Key secondary outcome(s))

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.

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

Healthy volunteers allowed

No

Age group

Adult

Sex

All

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

Fürth

Germany

90766

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 & Co. KG. (Germany)

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	22/07/2009		Yes	No