The efficacy and safety of cineole during long term treatment of patients with asthma

Submission date Recruitment status Prospectively registered 05/05/2009 No longer recruiting [] Protocol [] Statistical analysis plan Registration date Overall study status 11/05/2009 Completed [X] Results Individual participant data **Last Edited** Condition category 19/05/2022 Respiratory

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

Clinical Trials Information System (CTIS)

2006-001656-13

Protocol serial number

K/599

Study information

Scientific Title

Multicentre, randomised, double-blind, placebo-controlled parallel group comparison in order to prove efficacy and safety of cineole during long term treatment of patients with asthma

Study objectives

Concomitant therapy with cineole will improve lung function, symptoms and quality of life in patients with asthma.

Ethics approval required

Old ethics approval format

Ethics approval(s)

The ethics committee of the University Hospital Nuernberg-Erlangen and the ethics committees of the Medical Associations of Bayern, Hessen, Nordrhein, Westfalen and Hamburg all gave approval on the 19th October 2006

Study design

Multicentre randomised double-blind placebo-controlled parallel group comparison

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Asthma

Interventions

Cineole was given three times daily, two capsules with 100 mg cineole each, over a period of 6 months. The capsules in the placebo group were organoleptically identical but without any active ingredient.

Measurements of lung function by Spirometry, asthma symptoms and quality of life by the Asthma Questionnaire of Quality of Life (AQLQ).

Intervention Type

Drug

Phase

Phase III

Drug/device/biological/vaccine name(s)

Cineole

Primary outcome(s)

Composite scores of lung function parameters, asthma symptoms and quality of life. Assessments were initial visit and after 1, 2, 3, 4, 5 and 6 months.

Key secondary outcome(s))

- 1. Lung function (spirometry)
- 2. Asthma symptoms (dyspnoea, secretion, cough)
- 3. Quality of life (Asthma Questionnaire of Quality of Life [AQLQ])

Assessments were initial visit and after 1, 2, 3, 4, 5 and 6 months.

Completion date

28/01/2009

Eligibility

Key inclusion criteria

- 1. Patients with asthma for at least two years
- 2. Reversibility of greater than 15% after inhalation of beta-agonists
- 3. Aged greater than or equal to 18 and less than or equal to 70 years, either sex

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

Αll

Key exclusion criteria

- 1. Chronic obstructive pulmonary disease (COPD)
- 2. Co-medication with other mucolytics
- 3. Infection at the beginning of the study

Date of first enrolment

29/11/2006

Date of final enrolment

28/01/2009

Locations

Countries of recruitment

Germany

Study participating centre

Medizinische Klinik I

Fuerth 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

Not provided at time of registration

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Basic results		23/05/2021	19/05/2022	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes