ISRCTN90948816 https://doi.org/10.1186/ISRCTN90948816

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
Registration date	**Overall study status**	[_] Statistical analysis plan
11/05/2009	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
19/05/2022	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
2006-001656-13

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
GP practice

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

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 measure
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.

Secondary outcome measures
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.

Overall study start date
29/11/2006

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
240 patients

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
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Sponsor information

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

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Sponsor type
Research organisation

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
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