

A double blind, randomised, parallel group study evaluating the efficacy of a homeopathic remedy in asthma

Submission date 23/01/2004	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 23/01/2004	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 29/11/2013	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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

R/35/9.95/Holg

Study information

Scientific Title

Study objectives

The use of homoeopathy in the treatment of allergic disease remains controversial. Two recent reviews concluded that, of the numerous trials investigating homoeopathy, many were methodologically unsound. Numerous calls have been made for better designed and conducted studies in homoeopathy and other complementary therapies. Two such studies investigating the role of homoeopathy in patients with allergic rhinitis and asthma have been performed in Glasgow. Both of these randomised controlled trials reported a significant effect in favour of homoeopathy. This grant proposal aims to replicate the Glasgow findings in their asthma study using an identical treatment in a larger number of patients, and with greater statistical power. The protocol has been developed by extensive consultation within the research homoeopathic community, and will assess two main outcome measures, namely forced expiratory volume in one second (FEV1) and the percentage of asthma problem-free days (%PFD). In addition it will employ a number of secondary outcomes to assess well being with respect to asthma. It is anticipated that this trial will provide guidance on whether homoeopathy should be available as a new service provision to purchasers within the NHS, and as such will have significant resource implications for the NHS.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Study design

Randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Not specified

Study type(s)

Not Specified

Participant information sheet

Health condition(s) or problem(s) studied

Respiratory tract diseases: Asthma

Interventions

Participants were randomised to receive oral homeopathic immunotherapy or identical placebo

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

Clinical based assessments: forced expiratory volume in one second (FEV1), quality of life and mood. Diary based assessments: morning and evening peak expiratory flow, visual analogue scale of severity of asthma, quality of life and daily mood

Secondary outcome measures

Not provided at time of registration

Overall study start date

01/04/1996

Completion date

01/01/1999

Eligibility**Key inclusion criteria**

Aged 18-55, positive skin prick test to house dust mite, re-diagnosed asthma in response to bronchodilators and activity limited by asthma during pre-treatment baseline period

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Upper age limit

55 Years

Sex

Not Specified

Target number of participants

Not provided at time of registration

Key exclusion criteria

Previous drug trial within 30 days, previous treatment with homeopathic immunotherapy, pregnancy, respiratory tract infection within 3 weeks of recruitment or change in asthma medication in the 2 weeks prior to entry

Date of first enrolment

01/04/1996

Date of final enrolment

01/01/1999

Locations

Countries of recruitment

England

United Kingdom

Study participating centre

University of Southampton

Southampton

United Kingdom

SO14 0YG

Sponsor information

Organisation

NHS R&D Regional Programme Register - Department of Health (UK)

Sponsor details

The Department of Health

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Sponsor type

Government

Website

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Funder(s)

Funder type

Government

Funder Name

NHS Executive South West

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	02/03/2002		Yes	No