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A pilot study to investigate whether the homeopathic approach, in addition to standard care, can increase symptom free days and improve asthma control and quality of life in children with poorly controlled asthma

Submission date 29/09/2006	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 29/09/2006	**Overall study status** Completed	
Last Edited 28/09/2011	**Condition category** 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

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N0632177581

Study information

Scientific Title

Study objectives
Can homeopathy in addition to standard care, increase symptom free days and improve asthma control and quality of life in children with poorly controlled asthma?

Ethics approval required
Old ethics approval format

Ethics approval(s)
Added September 2008: favourable ethical opinion from the Oxfordshire Research Ethics Committee B (UK) on 22/11/2005.

Study design
Pilot RCT

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Quality of life

Participant information sheet

Health condition(s) or problem(s) studied
Respiratory: Asthma

Interventions
1. Homeopathy plus standard care
2. Standard care

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
As this is a pilot study there is no primary outcome measure. The research team are actively investigating whether subjective measures such as asthma control or asthma QOL or MYMOP or objective measures such as FEV1, antibiotic use will be most useful.

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/12/2005

Completion date
30/11/2006

Eligibility

Key inclusion criteria
The study aims to recruit 50-80 participants divided equally between intervention and control groups. Inclusion criteria: Children aged 7-14 years who are attending respiratory outpatients and who are at step 2 or step 3 or above on the British Thoracic Guidelines.

Participant type(s)
Patient

Age group
Child

Lower age limit
7 Years

Upper age limit
14 Years

Sex
Not Specified

Target number of participants
80

Key exclusion criteria
Children who are presently using homeopathy or who are too unwell to take part or refuse informed consent.

Date of first enrolment
01/12/2005

Date of final enrolment
30/11/2006

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Bristol Homeopathic Hospital
Bristol
United Kingdom
BS6 6JU

Sponsor information

Organisation
Record Provided by the NHSTCT Register - 2006 Update - Department of Health

Sponsor details
The Department of Health, Richmond House, 79 Whitehall
London
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+44 (0)20 7307 2622
dhmail@doh.gsi.org.uk

Sponsor type
Government

Website
http://www.dh.gov.uk/Home/fs/en

Funder(s)

Funder type
Government

Funder Name
Avon Primary Care Research Collaborative (UK) NHS R&D Support Funding

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	01/07/2011		Yes	No