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Safety of nebulised lignocaine in asthma

Submission date 23/01/2004	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 23/01/2004	**Overall study status** Completed	
Last Edited 09/12/2008	**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
RBF 96X33

Study information

Scientific Title

Study objectives
1. To determine the effect of single doses of nebulised lignocaine (80 mg and 160 mg) on FEV1, bronchial reactivity, heart rate, blood pressure and plasma lignocaine levels over 2 hours in patients with relatively mild asthma
2. To determine whether any tendency to bronchoconstriction with nebulised lignocaine can be prevented by pre-treatment with salbutamol

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
1. Placebo followed by 80 mg lignocaine
2. 2.5 mg salbutamol followed by 80 mg lignocaine
3. Placebo followed by placebo
4. Placebo followed by 160 mg lignocaine
5. 2.5 mg salbutamol followed by 160 mg lignocaine

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)

lignocaine, salbutamol

Primary outcome measure
Future work: if nebulised lignocaine can be confirmed to be safe and well tolerated either with or without pre-treatment with salbutamol the researchers intend to proceed with studies of regular treatment in subjects with more severe asthma to determine its steroid sparing effects.

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/02/1997

Completion date
31/07/1997

Eligibility

Key inclusion criteria
1. 20 patients aged 16 to 65 from the asthma research volunteers register.
2. They will have an forced expiratory volume in one second (FEV1) above 50% predicted, a history of asthma for at least 6 months (which is currently stable), at least 15% reversibility in FEV1 with 200 µg inhaled salbutamol, a PD20 methacholine, 12 µmol and they will be taking no treatment other than an inhaled steroid (up to 400 µg) and a short acting inhaled bronchodilator.

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
20

Key exclusion criteria
1. Any history of allergy to local anaesthetics, cardiac disease, epilepsy or other important medical condition
2. Women of child bearing age will only be included if surgically sterilised

Date of first enrolment
01/02/1997

Date of final enrolment
31/07/1997

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
University of Nottingham
Nottingham
United Kingdom
NG5 1PB

Sponsor information

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

Sponsor details
The Department of Health
Richmond House
79 Whitehall
London
United Kingdom
SW1A 2NL
+44 (0)20 7307 2622
dhmail@doh.gsi.org.uk

Sponsor type
Government

Website
http://www.doh.gov.uk

Funder(s)

Funder type
Government

Funder Name
NHS Executive Trent (UK)

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	01/12/1998		Yes	No