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A randomised controlled study of the effect of dietary sodium modification on asthma control

Submission date 02/08/2005	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 10/08/2005	**Overall study status** Completed	
Last Edited 07/05/2008	**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
Version 1

Study information

Scientific Title

Study objectives
Low dietary sodium improves asthma control.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval received from the MREC for Wales in September 2005 (ref: 05/MRE09/72).

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

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

Interventions
Low sodium diet versus normal sodium diet.

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Dietary sodium

Primary outcome measure

1. Bronchial reactivity, measured at baseline visit and six weeks later
2. Autonomic function assessed by heart rate variability, measured at baseline visit and six weeks later

Secondary outcome measures
1. Peak flow rate, measured for one week before baseline visit and for the six weeks of the study
2. Symptom score, measured for one week before baseline visit and for the six weeks of the study
3. Spirometry, measured at baseline visit and six weeks later
4. Skin prick sensitivity, measured at baseline visit and six weeks later
5. Carbon monoxide, measured at baseline visit and six weeks later

Overall study start date
01/01/2006

Completion date
01/12/2007

Eligibility

Key inclusion criteria
1. Aged 18 - 65 years, either sex
2. Asthma
3. Bronchial reactivity to methacholine

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
65 Years

Sex
Both

Target number of participants
220

Key exclusion criteria
1. Oral steroids
2. Diuretics or drug that affects sodium
3. Current or planned pregnancy
4. Other serious illness
5. Recent exacerbation of asthma

Date of first enrolment
01/01/2006

Date of final enrolment
01/12/2007

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Dept of Epidemiology and Public Health
Nottingham
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NG5 1PB

Sponsor information

Organisation
University of Nottingham (UK)

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Sponsor type
University/education

ROR
https://ror.org/01ee9ar58

Funder(s)

Funder type
Charity

Funder Name
Asthma UK (UK) (2005 grant)

Alternative Name(s)
Asthma UK, Asthma + Lung UK

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
United Kingdom

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	15/07/2008		Yes	No