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

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

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

Protocol serial number 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

Study type(s)

Treatment

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(s)

- 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

Key secondary outcome(s))

- 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

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Upper age limit

65 years

Sex

All

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

United Kingdom

England

Study participating centre Dept of Epidemiology and Public Health

Nottingham United Kingdom NG5 1PB

Sponsor information

Organisation

University of Nottingham (UK)

ROR

https://ror.org/01ee9ar58

Funder(s)

Funder type

Charity

Funder Name

Asthma UK (UK) (2005 grant)

Alternative Name(s)

asthmalunguk, Asthma UK, Asthma + Lung UK

Funding Body Type

Private sector organisation

Funding Body Subtype

Research institutes and centers

Location

United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	Results	15/07/2008		Yes	No