

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

Submission date 02/08/2005	Recruitment status No longer recruiting	☒ Prospectively registered ☐ Protocol
Registration date 10/08/2005	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 07/05/2008	Condition category Respiratory	☐ 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

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