

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

<b>Submission date</b> 02/08/2005	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 10/08/2005	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 07/05/2008	<b>Condition category</b> Respiratory	<input type="checkbox"/> 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

**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

United Kingdom

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?
<a href="#">Results article</a>	Results	15/07/2008		Yes	No