

Dietary magnesium or vitamin C supplementation as an adjunct to usual asthma therapy: a community-based investigation

Submission date 23/01/2004	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 23/01/2004	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 18/11/2009	Condition category Respiratory	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N/A

Study information

Scientific Title

Study objectives

Several characteristics of a "Western" diet, including low magnesium and low vitamin C intake, have been proposed to be risk factors for the occurrence and severity of asthma. If so then these effects could be extremely important in public health terms, since the relative ease, affordability and generalisability of dietary intervention could translate even very small effects at a personal level into substantial effects in terms of primary and secondary prevention across the general population. This trial is designed to determine whether magnesium or vitamin C supplementation can yield improvements in clinical control, quality of life and use of health care resources, and reductions in requirement for inhaled steroids, in typical patients with asthma drawn from general practice populations.

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)

GP practice

Study type(s)

Treatment

Participant information sheet

Health condition(s) or problem(s) studied

Respiratory tract diseases: Asthma

Interventions

1. Magnesium chelate 450 mg
2. Vitamin C 1 g
3. Placebo (lactose)

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

1. Clinical control
2. Quality of life
3. Use of health care resources
4. Reductions in requirement for inhaled steroids

Secondary outcome measures

Not provided at time of registration

Overall study start date

01/05/1998

Completion date

01/09/2000

Eligibility**Key inclusion criteria**

1. Patients with asthma on inhaled corticosteroids
2. Aged 18-60

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Upper age limit

60 Years

Sex

Both

Target number of participants

24 (Added 18/11/09)

Key exclusion criteria

1. Pregnancy
2. Oral steroids
3. Significant co-morbidity
4. Diuretics

Date of first enrolment

01/05/1998

Date of final enrolment

01/09/2000

Locations

Countries of recruitment

England

United Kingdom

Study participating centre

Division of Respiratory Medicine

Nottingham

United Kingdom

NG5 1PB

Sponsor information

Organisation

Record Provided by the NHS R&D 'Time-Limited' National Programme Register - Department of Health (UK)

Sponsor details

The Department of Health

Richmond House

79 Whitehall

London

United Kingdom

SW1A 2NL

Sponsor type

Government

Website

<http://www.doh.gov.uk>

Funder(s)

Funder type

Government

Funder Name

NHS Asthma National Research and Development Programme (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	01/10/2003		Yes	No