

Randomised double-blind, placebo-controlled trial of selenium supplementation in adult asthma

Submission date 26/04/2006	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 15/05/2006	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 31/05/2007	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
N0534164211

Study information

Scientific Title

Acronym

SELINA (SELEnium IN Asthma)

Study objectives

That a low intake of selenium, by increasing oxidative stress, promotes airway inflammation and worsens asthma symptoms, and that this effect can be ameliorated by supplementation with selenium, leading to a reduction in severity and even remission of asthma symptoms.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved by Greenwich Local Research Ethics Committee (LREC), main approval 21/11/01; amendments to protocol approved on 4/4/03, reference number: 82/NOV/01 and Guy's LREC main approval: 26/09/02; amendments to protocol approved on 19/11/02; 19/02/03; 15/05/03; reference number: 02/09/16

Study design

Randomised, double-blind, placebo-controlled trial (parallel design)

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Adult asthma

Interventions

Selenium supplement 100 microgram (one tablet per day) versus placebo supplied by Pharma Nord, Denmark. The product (SelenoPrecise™) is a yeast preparation grown in a selenium-rich medium. Placebo contains yeast only.

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

SelenoPrecise

Primary outcome(s)

Asthma-related quality of life

Key secondary outcome(s))

1. Lung function
2. Asthma symptom scores
3. Peak flow
4. Bronchodilator usage

Completion date

01/05/2005

Eligibility

Key inclusion criteria

1. Asthma symptoms in last month
2. Prescribed inhaled steroids in last six months
3. Not taking selenium supplements

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Key exclusion criteria

1. Inability to give informed consent
2. Inability to swallow tablets
3. Pregnancy or lactation or intention to become pregnant during the trial period
3. Renal or liver disease
4. Known yeast intolerance

Date of first enrolment

01/05/2002

Date of final enrolment

01/05/2005

Locations

Countries of recruitment

United Kingdom

England

Study participating centre

Imperial College London
London
United Kingdom
W2 1PG

Sponsor information

Organisation

Department of Health (UK)

ROR

<https://ror.org/03sbpja79>

Funder(s)

Funder type

Government

Funder Name

Department of Health Unit Grant, which core funds our Public Health Aspects of Asthma Research Programme (Social Medicine and Health Services Research Unit (ref: 121/7418, Unit Director and grant holder Prof P Burney).

Results and Publications

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		01/06/2007		Yes	No