

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

<b>Submission date</b> 26/04/2006	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 15/05/2006	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 31/05/2007	<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

### Contact name

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### Contact details

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## Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

## Secondary identifying numbers

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

## Secondary study design

Randomised controlled trial

## Study setting(s)

Not specified

## Study type(s)

Treatment

## Participant information sheet

## 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 measure**

Asthma-related quality of life

**Secondary outcome measures**

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

**Overall study start date**

01/05/2002

**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

**Age group**

Adult

**Sex**

Both

**Target number of participants**

200 (100 in each arm)

**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**

England

United Kingdom

**Study participating centre**

**Imperial College London**

London

United Kingdom

W2 1PG

## **Sponsor information**

**Organisation**

Department of Health (UK)

**Sponsor details**

Chief Research Officer for Public Health

Department of Health

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**Sponsor type**

Government

**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

**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>		01/06/2007		Yes	No