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

| Submission date | Recruitment status | [_] Prospectively registered |
|---|---|---|
| 26/04/2006 | No longer recruiting | [_] Protocol |
| **Registration date** | **Overall study status** | [_] Statistical analysis plan |
| 15/05/2006 | Completed | [X] Results |
| **Last Edited** | **Condition category** | [_] Individual participant data |
| 31/05/2007 | Respiratory | |

**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
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
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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? |
|---|---|---|---|---|---|
| Results article | | 01/06/2007 | | Yes | No |