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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

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

Primary study design
Interventional

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

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