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Selenium supplementation for the prevention of hepatocellular carcinomas in HBsAg positive patients (pilot study)

Submission date 06/06/2003	**Recruitment status** Stopped	[ ] Prospectively registered [ ] Protocol
Registration date 23/09/2003	**Overall study status** Stopped	[ ] Statistical analysis plan [ ] Results
Last Edited 18/10/2012	**Condition category** Cancer	[ ] Individual participant data [ ] Record updated in last year

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
N/A

Study information

Scientific Title

Study objectives
Not provided at time of registration

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)
Not specified

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Prevention of primary liver cancer with selenium supplementation - targeted to high risk population

Interventions
Eligible patients who consent to participate will be randomly allocated to the selenium group (oral selenium supplementation: 200mg selenium per day, in the form of selenized yeast tablet) or control group (receiving placebo).

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)

Selenium

Primary outcome measure
Not provided at time of registration

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/01/2000

Completion date
01/01/2002

Reason abandoned (if study stopped)
Lack of funding

Eligibility

Key inclusion criteria
Participants will include:
1. Men aged 45 to 64 with positive HBsAg (hepatitis B surface antigen) test
2. Negative AFP (alphafetoprotein) test
3. Normal ALT (alanine aminotransferase) values

Participant type(s)
Patient

Age group
Adult

Sex
Male

Target number of participants
Not provided at time of registration

Key exclusion criteria
Not provided at time of registration

Date of first enrolment
01/01/2000

Date of final enrolment
01/01/2002

Locations

Countries of recruitment

England

United Kingdom

Study participating centre
Department of Public Health & Epidemiology
Birmingham
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Sponsor information

Organisation
The University of Birmingham (UK)

Sponsor details
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Sponsor type
University/education

ROR
https://ror.org/03angcq70

Funder(s)

Funder type
University/education

Funder Name
University of Birmingham (UK) - The Department of Public Health and Epidemiology is supporting the pilot phase of this study

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