

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

Submission date 06/06/2003	Recruitment status Stopped	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 23/09/2003	Overall study status Stopped	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 18/10/2012	Condition category Cancer	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> 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

Protocol serial number
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

Study type(s)

Treatment

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(s)

Not provided at time of registration

Key secondary outcome(s)

Not provided at time of registration

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

Healthy volunteers allowed

No

Age group

Adult

Sex

Male

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

United Kingdom

England

Study participating centre

Department of Public Health & Epidemiology

Birmingham

United Kingdom

B15 2TT

Sponsor information

Organisation

The University of Birmingham (UK)

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

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration