ISRCTN26633557 https://doi.org/10.1186/ISRCTN26633557

Selenium supplementation in euthyroid patients with thyroid peroxidase antibodies

Submission date	Recruitment status	[ ] Prospectively registered
12/09/2005	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
12/09/2005	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
03/07/2009	Nutritional, Metabolic, Endocrine	[ ] 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
NTR87; MEC number: 04/072

Study information

Scientific Title

Study objectives
Not provided at time of registration

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval received from the local medical ethics committee

Study design
Randomised double blind, active controlled, parallel group trial

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
Euthyroidism

Interventions
Selenium supplementation or placebo

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
1. Change of TPO-antibody concentration,
2. Difference in TSH level

Secondary outcome measures
1. Development of subclinical or overt hypothyroidism
2. Quality of life estimation

Overall study start date

01/08/2005

Completion date
31/07/2007

Eligibility

Key inclusion criteria
1. Thyroid peroxidase antibodies greater than 100 kU/l
2. Thyroid stimulating hormone (TSH) 0.4 - 4.0 mE/L
3. Free thyroxine (FT4) 10 - 23 pmol/l
4. Triiodothyronine (T3) 1.30 - 2.70 nmol/L
5. Female sex

Participant type(s)
Patient

Age group
Not Specified

Sex
Female

Target number of participants
150

Key exclusion criteria
1. Use of multivitamin tablets containing selenium in the month preceding inclusion
2. Drug or alcohol abuse
3. No informed consent

Date of first enrolment
01/08/2005

Date of final enrolment
31/07/2007

Locations

Countries of recruitment
Netherlands

Study participating centre
Academic Medical Centre
Amsterdam
Netherlands
1105 AZ

Sponsor information

Organisation
Academic Medical Centre (AMC) (Netherlands)

Sponsor details
Department of Internal Medicine
Meibergdreef 9
Amsterdam
Netherlands
1100 DD

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/03t4gr691

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Academic Medical Centre (AMC) (Netherlands)

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