

A randomised placebo controlled double blind clinical trial comparing selenium and pentoxifylline in patients with mild Graves' orbitopathy - EUGOGO study B

Submission date 14/02/2006	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 14/02/2006	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 04/08/2008	Condition category Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<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

MEC 03/119; NTR524

Study information

Scientific Title

Acronym

EUGOGO study B

Study objectives

Antioxidants or anticytokines may suppress the autoimmune reaction in orbital tissues in Graves' orbitopathy patients.

Null hypothesis:

Selenium and pentoxifylline are as effective as placebo in mild Graves' orbitopathy.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics approval received from the local ethics committee

Study design

Multicentre, randomised, placebo controlled, double blind, parallel group trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Graves' orbitopathy

Interventions

Group A: pentoxifylline 600 mg twice daily orally for 6 months

Group B: selenium selenite 100 µg twice daily orally for 6 months

Group C: placebo twice daily orally for 6 months

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Selenium, pentoxifylline

Primary outcome(s)

Improvement in:

1. Lid aperture of at least 2 mm
2. Any of the class 2 signs by at least 1 grade
3. Proptosis by at least 2 mm

4. Any duction by at least 8 degrees
5. Improvement of 6 or more points on the Graves' Ophthalmopathy Quality Of Life Questionnaire (GO-QOL) scales

Key secondary outcome(s))

Improvement in:

1. The Gorman diplopia score
2. The 7 first items of the clinical activity score

Completion date

01/11/2008

Eligibility

Key inclusion criteria

1. Graves' hyperthyroidism, euthyroid for at least two months by antithyroid drugs or surgery (at least 6 months if I131 is used)
2. Mild Graves' ophthalmopathy (at least 1 sign), with a disease duration of less than 18 months
3. No past treatment of the ophthalmopathy except for local measures
4. Aged 18 - 70 years

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

Key exclusion criteria

1. NOSPECS class 2c
2. Proptosis greater than 22 mm
3. Diplopia in primary or reading position and/or ocular torticollis
4. Mono-ocular duction in any direction of less than 20 degrees
5. Optic nerve involvement
6. Pregnancy, drugs/alcohol abuse, severe concomitant illness, no informed consent, use of selenium or pentoxifylline containing preparations

Date of first enrolment

01/11/2004

Date of final enrolment

01/11/2008

Locations

Countries of recruitment

Netherlands

Study participating centre

Academic Medical Centre

Amsterdam

Netherlands

1105 AZ

Sponsor information

Organisation

Academic Medical Centre (AMC) (The Netherlands)

ROR

<https://ror.org/03t4gr691>

Funder(s)

Funder type

Other

Funder Name

Expenses are being covered by the individual participating hospitals (The Netherlands)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration