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

Submission date	Recruitment status	<ul><li>Prospectively registered</li></ul>
14/02/2006	No longer recruiting	☐ Protocol
Registration date	Overall study status	Statistical analysis plan
14/02/2006	Completed	Results
Last Edited	Condition category	Individual participant data
04/08/2008	Nutritional, Metabolic, Endocrine	<ul><li>Record updated in last year</li></ul>

#### Plain English summary of protocol

Not provided at time of registration

# **Contact information**

## Type(s)

Scientific

#### Contact name

Prof W.M. Wiersinga

#### Contact details

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## Additional identifiers

**EudraCT/CTIS** number

**IRAS** number

ClinicalTrials.gov number

Secondary identifying numbers

# 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 pentoxifilline 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

#### Secondary study design

Randomised controlled trial

#### Study setting(s)

Hospital

#### Study type(s)

Treatment

#### Participant information sheet

#### 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 measure

Improvement in:

- 1. Lid apperture 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

#### Secondary outcome measures

Improvement in:

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

#### Overall study start date

01/11/2004

#### 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** 

#### Age group

Adult

#### Lower age limit

18 Years

#### Sex

Both

#### Target number of participants

156

#### 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)

#### Sponsor details

Department of Endocrinology and Metabolism P.O. Box 22660 Amsterdam Netherlands 1100 DD

#### Sponsor type

Hospital/treatment centre

#### Website

http://www.amc.uva.nl

#### **ROR**

# Funder(s)

## Funder type

Other

#### Funder Name

Expenses are being covered by the individual participating hospitals (The 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