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

No registrations found.

| | |
|---|---|
| **Ethical review** | Positive opinion |
| **Status** | Recruiting |
| **Health condition type** | - |
| **Study type** | Interventional |

## Summary

### ID

NL-OMON24865

**Source**
Nationaal Trial Register

**Brief title**
EUGOGO study B

**Health condition**

Mild Graves' orbitopathy

### Sponsors and support

**Primary sponsor:** Prof. dr. W.M. Wiersinga
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**Source(s) of monetary or material Support:** none

## Intervention

## Outcome measures

### Primary outcome

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 GO-QOL scales.

### Secondary outcome

Improvement in:
1. The Gorman diplopia score;
2. the 7 first items of the clinical activity score.

# Study description

### Background summary

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

### Study objective

Antioxidants or anticytokines may suppress the autoimmune reaction in orbital tissues in Graves' orbitopathy patients.
Nul hypothesis: selenium and pentoxifilline are as effective as placebo in mild Graves' orbitopathy.

### Intervention

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

# Contacts

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# Eligibility criteria

## Inclusion criteria

1. Graves' hyperthyroidism, euthyroid for at least two months by antithyroid drugs of 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. Age 18-70 years.

## Exclusion criteria

1. NOSPECS class 2c;
2. Proptosis >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.

# Study design

## Design

| | |
|---|---|
| Study type: | Interventional |
| Intervention model: | Parallel |
| Masking: | Double blinded (masking used) |
| Control: | Placebo |

## Recruitment

NL

| | |
|---|---|
| Recruitment status: | Recruiting |
| Start date (anticipated): | 01-11-2004 |
| Enrollment: | 156 |
| Type: | Anticipated |

# Ethics review

Positive opinion

| | |
|---|---|
| Date: | 01-12-2005 |
| Application type: | First submission |

# Study registrations

## Followed up by the following (possibly more current) registration

No registrations found.

## Other (possibly less up-to-date) registrations in this register

No registrations found.

## In other registers

| Register | ID |
|---|---|
| NTR-new | NL482 |
| NTR-old | NTR524 |
| Other | : MEC 03/119 |
| ISRCTN | ISRCTN16320108 |

# Study results

**Summary results**
N/A