

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

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

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON24865

Bron

Nationaal Trial Register

Verkorte titel

EUGOGO study B

Aandoening

Mild Graves' orbitopathy

Ondersteuning

Primaire sponsor: Prof. dr. W.M. Wiersinga

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Overige ondersteuning: none

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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.

Toelichting onderzoek

Achtergrond van het onderzoek

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

Doel van het onderzoek

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.

Onderzoeksproduct en/of interventie

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

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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. Age 18-70 years.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Blinding:	Dubbelblind
Controle:	Placebo

Deelname

Nederland	
Status:	Werving gestart
(Verwachte) startdatum:	01-11-2004
Aantal proefpersonen:	156
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies	
Datum:	01-12-2005
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register

NTR-new

NTR-old

Ander register

ISRCTN

ID

NL482

NTR524

: MEC 03/119

ISRCTN16320108

Resultaten

Samenvatting resultaten

N/A