Comparison of the effectiveness and tolerability of different doses of intravenous glucocorticoid for the treatment of moderately severe Graves' ophthalmopathy. EUGOGO study C

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The hypothesis is that cummulative doses of 2.5, 5.0 or 7.5 gram methylprednisolone infusions are equally effective in moderately severe Graves' ophthalmopathy, but that the doses differ in the number and severity of side effects.

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

Samenvatting

ID

NL-OMON20884

Bron
NTR

Verkorte titel
EUGOGO study C

Aandoening

Moderately severe Graves' orbitopathy

Ondersteuning

Primaire sponsor: Prof. dr. W.M. Wiersinga
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Overige ondersteuning: none

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

1. Efficacy
Improvement in:
a. lid aperture of at least 3 mm
b. 2 or more degrees of class 2 signs
c. proptosis by at least 2 mm
d. any duction by at least 8 degrees or improvement in diplopia score
e. CAS by at least 2 points
f. improvement of 6 or more points on the GO-QOL scales.
2. Safety
safety score (2 points to each major side effect and 1 point to each minor side effect).

Toelichting onderzoek

Achtergrond van het onderzoek

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Doel van het onderzoek

The hypothesis is that cummulative doses of 2.5, 5.0 or 7.5 gram methylprednisolone infusions are equally effective in moderately severe Graves' ophthalmopathy, but that the doses differ in the number and severity of side effects.

Onderzoeksproduct en/of interventie

Treatment with weekly methylprednisolone iv infusions, total dose 2.5, 5.0 or 7.5 gram during 12 weeks

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. Moderately severe Graves' ophthalmopathy defined as having at least one of the following signs:
a. class 2b-c
b. mono-ocular duction <30 degrees
c. diplopia Gorman score grade a-c;
3. Active Graves' ophthalmopathy (CAS 3 or higher out of 7);
4. No past treatment of the ophthalmopathy except for local measures;
5. Age 18-70 years.

Belangrijkste redenen om niet deel te kunnen nemen

(Exclusiecriteria)

1. CAS <3;
2. Clinically relevant optic nerve involvement;
3. General contra-indications to glucocorticoid infusions;
4. Pregnancy;
5. No informed consent;
6. Viral hepatitis;
7. Liver enzymes increased by a factor 2.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Blindering:	Dubbelblind
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	21-09-2005
Aantal proefpersonen:	159
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	ID
NTR-new	NL483
NTR-old	NTR525
Ander register	: MEC 05/101
ISRCTN	ISRCTN17061437

Resultaten

Samenvatting resultaten
N/A