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

No registrations found.

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

Summary

ID

NL-OMON20884

Source
NTR

Brief title
EUGOGO study C

Health condition

Moderately severe 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

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).

Secondary outcome

N/A

Study description

Background summary

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

Study objective

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.

Intervention

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

Contacts

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Eligibility criteria

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. 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.

Exclusion criteria

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.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Masking:	Double blinded (masking used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	21-09-2005
Enrollment:	159
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	NL483
NTR-old	NTR525
Other	: MEC 05/101
ISRCTN	ISRCTN17061437

Study results

Summary results
N/A