

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

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Prof W.M. Wiersinga

Contact details
Academic Medical Centre
P.O. Box 22660
Amsterdam
Netherlands
1105 AZ
w.m.wiersinga@amc.uva.nl

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

MEC 05/101; NTR525

Study information

Scientific Title

Acronym

EUGOGO study C

Study objectives

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

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics approval received from the local ethics committee

Study design

Multicentre, randomised, double blinded, active controlled, 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

Moderately severe Graves' orbitopathy

Interventions

Treatment with weekly methylprednisolone intravenous (iv) infusions, total dose 2.5, 5.0 or 7.5 g for 12 weeks.

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Methylprednisolone

Primary outcome measure

1. Efficacy: improvement in:
 - 1.1. Lid aperture of at least 3 mm
 - 1.2. Two or more degrees of class 2 signs
 - 1.3. Proptosis by at least 2 mm
 - 1.4. Any duction by at least 8 degrees or improvement in diplopia score
 - 1.5. CAS by at least 2 points
 - 1.6. 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 measures

No secondary outcome measures

Overall study start date

21/09/2005

Completion date

01/10/2008

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. Moderately severe Graves' ophthalmopathy defined as having at least one of the following signs:
 - 2.1. Class 2b-c
 - 2.2. Mono-ocular duction less than 30 degrees
 - 2.3. Diplopia Gorman score grade a-c
3. Active Graves' ophthalmopathy (Clinical Activity Score [CAS] 3 or higher out of 7)
4. No past treatment of the ophthalmopathy except for local measures
5. Aged 18 - 70 years

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

159

Key exclusion criteria

1. CAS less than 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 of 2

Date of first enrolment

21/09/2005

Date of final enrolment

01/10/2008

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

<https://ror.org/03t4gr691>

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