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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	Recruitment status	[ ] Prospectively registered
14/02/2006	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
14/02/2006	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
04/08/2008	Nutritional, Metabolic, Endocrine	[ ] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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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