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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
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

Primary study design
Interventional

Study design
Multicentre, randomised, double blinded, active controlled, parallel group trial

Study type(s)
Treatment

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(s)
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)

Key secondary outcome(s)
No secondary outcome measures

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

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

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)

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

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration