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A randomised placebo controlled double blind clinical trial comparing selenium and pentoxifylline in patients with mild Graves' orbitopathy - EUGOGO study B

Submission date
14/02/2006

Recruitment status
No longer recruiting

Registration date
14/02/2006

Overall study status
Completed

Last Edited
04/08/2008

Condition category
Nutritional, Metabolic, Endocrine

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] 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

Protocol serial number
MEC 03/119; NTR524

Study information

Scientific Title

Acronym
EUGOGO study B

Study objectives
Antioxidants or anticytokines may suppress the autoimmune reaction in orbital tissues in Graves' orbitopathy patients.

Null hypothesis:
Selenium and pentoxifilline are as effective as placebo in mild Graves' orbitopathy.

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, placebo controlled, double blind, parallel group trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Graves' orbitopathy

Interventions
Group A: pentoxifylline 600 mg twice daily orally for 6 months
Group B: selenium selenite 100 µg twice daily orally for 6 months
Group C: placebo twice daily orally for 6 months

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Selenium, pentoxifylline

Primary outcome(s)
Improvement in:
1. Lid apperture of at least 2 mm
2. Any of the class 2 signs by at least 1 grade
3. Proptosis by at least 2 mm

4. Any duction by at least 8 degrees
5. Improvement of 6 or more points on the Graves' Ophthalmopathy Quality Of Life Questionnaire (GO-QOL) scales

Key secondary outcome(s)
Improvement in:
1. The Gorman diplopia score
2. The 7 first items of the clinical activity score

Completion date
01/11/2008

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. Mild Graves' ophthalmopathy (at least 1 sign), with a disease duration of less than 18 months
3. No past treatment of the ophthalmopathy except for local measures
4. 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. NOSPECS class 2c
2. Proptosis greater than 22 mm
3. Diplopia in primary or reading position and/or ocular torticollis
4. Mono-ocular duction in any direction of less than 20 degrees
5. Optic nerve involvement
6. Pregnancy, drugs/alcohol abuse, severe concomitant illness, no informed consent, use of selenium or pentoxifylline containing preparations

Date of first enrolment
01/11/2004

Date of final enrolment
01/11/2008

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