The effects of squint surgery on double vision and abnormal head posture in patients with Graves eye disease.

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON22894

Source
NTR

Brief title
GINTS study

Health condition

Graves'orbitopathy
strabismus surgery
Quality of life

Sponsors and support

Primary sponsor: none
Source(s) of monetary or material Support: none

Intervention

Outcome measures

Primary outcome

Primary outcome measure will be the correlation between the changes in the field of BSV and

QoL.

Secondary outcome

Secondary outcomes will be the influence on primary outcome of squint angle, ductions and cyclodeviation. Also, the influence of prior treatment (for instance orbital decompression) on field of BSV, change in proptosis and lid aperture and the number of complications will be recorded.

Study description

Background summary

To evaluate the outcome of strabismus surgery in Graves' Orbitopathy patients on binocular function and quality of life.

Study objective

There is a significant correlation between the changes in the field of binocular single vision and the quality of life measured with the GO-QoL and the TED-QoL.

Study design

3 months postoperatively.

Intervention

Strabismus surgery.

Contacts

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Eligibility criteria

Inclusion criteria

1. GO-patients, who are clinically and biochemically euthyroid for at least three months;

2. GO-patients, who show a stable orthoptic picture for at least three months: Stable means no greater than 5 prism dioptres change in primary position and no greater change in duction as 8°.

Exclusion criteria

1. GO-patients with suppression (inhibition of the image of the deviating eye in the visual cortex);

2. Presence of previously diagnosed and/or treated for squint not related to the thyroid;

3. Presence of vision less than 0,2 for one or both eyes.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	31-01-2013
Enrollment:	40
Type:	Anticipated

Ethics review

Positive opinion

Date:	18-01-2013
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	NL3644
NTR-old	NTR3796
Other	AMC : 1001
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A