

A randomized comparison of bilateral recession with unilateral recession-resection as surgery for infantile esotropia.

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON24936

Source

NTR

Brief title

BR vs RR

Health condition

Infantile esotropia.

Sponsors and support

Source(s) of monetary or material Support: Algemene Nederlandse vereniging ter voorkoming van blindheid
Afdeling Oogheelkunde Erasmus MC.

Intervention

Outcome measures

Primary outcome

The variation of the latent angle of strabismus at distance at three months postoperatively between BR and RR.

Secondary outcome

Reduction of convergence excess (larger angle of strabismus during near vision) Binocular vision by means of Bagolini striated glasses.

Study description

Background summary

N/A

Study objective

Infantile esotropia is corrected in most cases by bilateral recession of the medial rectus muscles (BR) or by unilateral recession of the medial rectus muscle and resection of the lateral rectus muscle (RR). The preference of BR or RR is subject of discussion and none of the many arguments have been validated. We compared the outcome of these techniques in a study.

Study design

N/A

Intervention

Bilateral recession of the medial rectus muscles (BR) and unilateral recession of the medial rectus muscle and resection of the lateral rectus muscle (RR).

Contacts

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Eligibility criteria

Inclusion criteria

Eligible were all children aged three to eight years with a normal psychophysical development, and onset of esotropia before age 1 who visited one of the clinics during the study period.

Exclusion criteria

Previous strabismus surgery, an angle of strabismus larger than 24° or smaller than 10°, any normal binocular vision, convergence excess with angle of strabismus at near fixation 1.5 times larger than the angle at distance, more than 1 line Logmar acuity difference between the two eyes, hypermetropia over 6 diopters or myopia over 3 diopters, up- or downshoot in (25°) adduction more than 8°, V-pattern (25° up and down gaze) over 8°, A-pattern (25° up and down gaze) over 5° and manifest vertical strabismus over 4°.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active

Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	01-01-1998
Enrollment:	124
Type:	Actual

Ethics review

Positive opinion	
Date:	09-09-2005
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	NL295
NTR-old	NTR333
Other	: N/A
ISRCTN	ISRCTN72461159

Study results

Summary results

N/A