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Bilateral recession or unilateral recession-resection as surgery for infantile esotropia

Submission date	Recruitment status	[ ] Prospectively registered
20/12/2005	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
20/12/2005	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
28/01/2009	Eye Diseases	[ ] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Prof H J Simonsz

Contact details
Erasmus Medical Centre Rotterdam
Department of Ophthalmology
Room Ba 104
P.O. Box 2040
Rotterdam
Netherlands
3015 GD
simonsz@compuserve.com

Additional identifiers

Protocol serial number
NTR333

Study information

Scientific Title
A randomised comparison of bilateral recession with unilateral recession-resection as surgery for infantile esotropia

Acronym
BR vs RR

Study objectives
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.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Received from the local ethics committee

Study design
Multicentre randomised single-blind active controlled parallel group trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Infantile esotropia

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

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
The variation of the latent angle of strabismus at distance at three months post-operatively between BR and RR.

Key secondary outcome(s))
1. Reduction of convergence excess (larger angle of strabismus during near vision)
2. Binocular vision by means of Bagolini striated glasses

Completion date
31/12/2001

Eligibility

Key inclusion criteria
Eligible were all children aged three to eight years (either sex) with a normal psychophysical development, and onset of esotropia before one year of age who visited one of the clinics during the study period.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Child

Lower age limit
3 years

Upper age limit
8 years

Sex
All

Key exclusion criteria
1. Previous strabismus surgery
2. An angle of strabismus larger than 24° or smaller than 10°
3. Any normal binocular vision
4. Convergence excess with angle of strabismus at near fixation 15 times larger than the angle at distance
5. More than 1 line Logmar acuity difference between the two eyes
6. Hypermetropia over 6 diopters or myopia over 3 diopters
7. Up or down shoot in (25°) adduction more than 8°
8. V-pattern (25° up and down gaze) over 8°
9. A-pattern (25° up and down gaze) over 5°
10. Manifest vertical strabismus over 4°

Date of first enrolment
01/01/1998

Date of final enrolment
31/12/2001

Locations

Countries of recruitment
Netherlands

Study participating centre

Erasmus Medical Centre Rotterdam
Rotterdam
Netherlands
3015 GD

Sponsor information

Organisation
Erasmus Medical Centre (Netherlands)

ROR
https://ror.org/018906e22

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Erasmus Medical Centre (Netherlands)

Funder Name
General Dutch Association Preventing Blindness (Algemene Nederlandse vereniging ter voorkoming van blindheid) (Netherlands)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration