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

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

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 measure
The variation of the latent angle of strabismus at distance at three months post-operatively between BR and RR.

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

Overall study start date
01/01/1998

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

Age group
Child

Lower age limit
3 Years

Upper age limit
8 Years

Sex
Both

Target number of participants
124

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)

Sponsor details
Dr Molewaterplein 40/50
Rotterdam
Netherlands
3000 CA

Sponsor type
University/education

Website
http://www.erasmusmc.nl/

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

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration