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An External Pilot Study to Test the Feasibility of a Randomised Controlled Trial comparing Eye Muscle Surgery against Active Monitoring for Childhood Intermittent Distance Exotropia [X (T)]

Submission date 22/03/2011	**Recruitment status** No longer recruiting	[X] Prospectively registered [X] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 22/03/2011	**Overall study status** Completed	
Last Edited 26/05/2015	**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
9967; HTA 09/01/20

Study information

Scientific Title
An External Pilot Study to Test the Feasibility of a Randomised Controlled Trial comparing Eye Muscle Surgery against Active Monitoring for Childhood Intermittent Distance Exotropia [X(T)]

Acronym
Pilot RCT comparing Surgery to Observation for Intermittent Exotropia

Study objectives
The aim is to design and conduct a randomised controlled trial of the clinical and cost effectiveness of immediate surgical treatment versus active monitoring in the management of intermittent exotropia in children under 16.

More details can be found at http://www.nets.nihr.ac.uk/projects/hta/090120
Protocol can be found at http://www.nets.nihr.ac.uk/__data/assets/pdf_file/0009/53100/PRO-09-01-20.pdf

Ethics approval required
Old ethics approval format

Ethics approval(s)
10/H0904/57

Study design
Randomised; Interventional; Design type: Not specified, Treatment

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Topic: Eye; Subtopic: Eye (all Subtopics); Disease: Ophthalmology

Interventions
Eye muscle surgery

Intervention Type
Procedure/Surgery

Primary outcome measure
Number of patients; Timepoint(s): To determine whether participating centres are likely to recruit a sufficient number of patients

Secondary outcome measures
1. Pilot procedures; Timepoint(s): To pilot procedures involved in the trial including recruitment, randomisation, surgery and masking
2. Questionnaires; Timepoint(s): To identify through questionnaires reasons why parents decline permission to participate
3. Recruited patients; Timepoint(s): To determine whether recruited patients remain in allocated groups

Overall study start date
01/09/2011

Completion date
01/12/2013

Eligibility

Key inclusion criteria
1. Age = 6 months and = 16 years
2. Diagnosis of Intermittent Exotropia on the basis of parental history and clinical examination within 6 months of recruitment
3. Newcastle Control Score of = 3
4. Minimum size of squint of 15 prism dioptres
5. If aged 4 years and over evidence of near stereopsis i.e. ability to use the eyes together
Target Gender: Male & Female; Upper Age Limit 16 years ; Lower Age Limit 6 months

Participant type(s)
Patient

Age group
Child

Lower age limit
6 Years

Upper age limit
16 Years

Sex
Both

Target number of participants
Planned Sample Size: 240; UK Sample Size: 144

Key exclusion criteria
1. Age under 6 months or over 16 years
2. Previous treatment for Intermittent Exotropia
3. Constant exotropia = 10 prism dioptres
4. Constant exotropia < 10 prism dioptres with absent near stereopsis
5. Intermittent Exotropia where near misalignment is = 10 prism dioptres more than the distance misalignment (Convergence insufficiency)
6. blyopia (poor vision) > 0.5 LogMAR in either eye
7. Structural ocular pathology
8. Significant neurodevelopmental delay
9. Families requiring translation services

Date of first enrolment
01/09/2011

Date of final enrolment
01/12/2013

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Royal Victoria Infirmary
Newcastle Upon Tyne
United Kingdom
NE1 4LP

Sponsor information

Organisation
Newcastle upon Tyne Hospitals NHS Foundation Trust (UK)

Sponsor details
Claremont Wing, Royal Victoria Infirmary , Queen Victoria Road
Newcastle Upon Tyne
England
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NE1 4LP

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/05p40t847

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research (NIHR) (UK)

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	16/10/2012		Yes	No
Results article	results	01/05/2015		Yes	No