

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	☒ Prospectively registered ☒ Protocol
Registration date 22/03/2011	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 26/05/2015	Condition category Eye Diseases	☐ Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
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

Primary study design

Interventional

Study design

Randomised; Interventional; Design type: Not specified, Treatment

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Child

Lower age limit

6 Years

Upper age limit

16 Years

Sex

All

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

United Kingdom

England

Study participating centre

Royal Victoria Infirmary

Newcastle Upon Tyne

United Kingdom

NE1 4LP

Sponsor information

Organisation

Newcastle upon Tyne Hospitals NHS Foundation Trust (UK)

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

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?
Results article	results	01/05/2015		Yes	No
Protocol article	protocol	16/10/2012		Yes	No