A randomised controlled trial of treatment of unilateral straight eyed visual acuity deficit

Prospectively registered Submission date Recruitment status 23/01/2004 No longer recruiting [] Protocol [] Statistical analysis plan Registration date Overall study status 23/01/2004 Completed [X] Results Individual participant data **Last Edited** Condition category 09/11/2022 **Eve Diseases**

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

RRCC7R R1903/6624

Study information

Scientific Title

A randomised controlled trial of treatment of unilateral straight eyed visual acuity deficit

Study objectives

Not provided at time of registration

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Study design

Randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Not specified

Study type(s)

Not Specified

Participant information sheet

Health condition(s) or problem(s) studied

Eye diseases

Interventions

The effects of correction of refractive error, alone and in combination with patching will be compared to no treatment.

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

The main outcome measure at both the preliminary and final analysis will be LogMAR acuity. Anova will be used to test the effect of group and sub-group analyses will test for heterogeneity between and at different initial acuities.

Secondary outcome measures

Not provided at time of registration

Overall study start date

28/02/1999

Completion date

28/02/2002

Eligibility

Key inclusion criteria

Children aged 3-4 years, with lateral visual acuity defects of 6/9 to 6/24.

Participant type(s)

Patient

Age group

Child

Lower age limit

3 Years

Upper age limit

4 Years

Sex

Not Specified

Target number of participants

Not provided at time of registration

Key exclusion criteria

Not provided at time of registration

Date of first enrolment

28/02/1999

Date of final enrolment

28/02/2002

Locations

Countries of recruitment

England

United Kingdom

Study participating centre

Royal Victoria Infirmary

Newcastle upon Tyne United Kingdom NE1 4LP

Sponsor information

Organisation

NHS R&D Regional Programme Register - Department of Health (UK)

Sponsor details

The Department of Health Richmond House 79 Whitehall London United Kingdom SW1A 2NL +44 (0)20 7307 2622 dhmail@doh.gsi.org.uk

Sponsor type

Government

Website

http://www.doh.gov.uk

Funder(s)

Funder type

Government

Funder Name

NHS Executive Northern and Yorkshire (UK)

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

Not provided at time of registration

IPD sharing plan summaryNot provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Other publications		29/11/2003		Yes	No
Other publications		01/08/2004		Yes	No
Results article		01/01/2005		Yes	No
Other publications		01/07/2006		Yes	No