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

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

Not 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