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Double-masked randomised controlled trial of an amblyopia treatment

Submission date 30/09/2005	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 30/09/2005	**Overall study status** Completed	
Last Edited 04/04/2013	**Condition category** Eye Diseases	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Prof Bruce Evans

Contact details
Institute of Optometry
56-62 Newington Causeway
London
United Kingdom
SE1 6DS
+44 (0)20 7407 4183
bruce.evans@virgin.net

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
M0003101241

Study information

Scientific Title

Study objectives
Amblyopia has a prevalence of 1-4% and is the leading cause of monocular visual loss in the age group 20-70 years (Simons, 1996) . Since AD 900 (Thabit Ibn Qurrah, 900), amblyopia has been treated by occluding the eye with better acuity. Although the lack of randomised controlled trials (RCTs) has been criticised (Moseley et al., 1995), this form of treatment is widely accepted clinically as long as the patient is treated within the so-called 'sensitive period' or 'critical period' of relatively high neural plasticity (Nelson, 1989).

Evans et al. (1999) carried out a clinical audit of Mallett's IPS treatment for amblyopia. The mean improvement was two lines of the Snellen chart and 100% of this improvement had occurred after 5 treatment sessions.

The purpose of the current study is to compare the Mallett IPS treatment with a placebo, using a randomised double-masked protocol.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Added 28 July 2008:
Received from City University and Institute of Optometry .

Study design
Double-masked 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
Full verbal and written information is provided to each participant and is available on request.

Health condition(s) or problem(s) studied
Eye Diseases: Amblyopia

Interventions

Patients meeting strict diagnostic criteria for amblyopia are randomly allocated to an experimental and a control group. The control treatment (modified CAM) was developed to give subjects the same degree of time, attention, and use of 'high-tech' equipment as the IPS treatment, but to have no features which are likely to generate a treatment effect. A two-interval 26 alternative forced choice method is used to measure LogMAR acuities on three consecutive weekly occasions before treatment. Subjects are then treated for 6 weeks and, a week after the final treatment, acuities are again measured but by a researcher who does not know which treatment the subjects have received.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
A table of findings will be drawn up describing the characteristics of the participants in the experimental group (e.g., age of onset, type of amblyopia, age at treatment) and participants will be ranked in this table in terms of their improvement in VA following treatment (based on their own z-score of improvement). The data will be inspected to see if there are any trends whereby particular types or sub-groups of amblyopia improve with IPS.

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/11/2001

Completion date
31/12/2010

Eligibility

Key inclusion criteria
Subjects will be aged 10-65 years. Visual acuity between 6/9 and 6/36 in the amblyopic eye and 6/6 or better in the good eye and where the amblyopia is the result of strabismus or anisometropia. Participants will meet the following selection criteria:

1. No personal history of epilepsy.
2. Willing to attend the Institute of Optometry for the three pre-treatment assessments, six treatment sessions, the post treatment assessment, and the follow-up assessment.
3. Unilateral amblyopia with visual acuity better than 6/36 but worse than 6/9 in the amblyopic eye and 6/6 or better in the non-amblyopic eye.
4. Amblyogenic factor: amblyopic eye is either strabismic or has at least 1D more hypermetropia or 2D more astigmatism than the non-amblyopic eye.
5. No ophthalmoscopically detectable anomalies of fundus or defects of the visual pathway. This will be taken to mean no clinically significant departure from a normal ophthalmoscopic appearance and 30 degrees visual fields (static perimetry) within normal limits.
6. Patients must be at least 10 years old and have signed the informed consent form, or have this signed by a parent or guardian if under 16 years old.

7. No history of strabismus or other cause of reduced visual acuity (e.g., cataract) in first two years of life.
8. Subjects must have had a recent (within the last 1 year) eye examination and must be wearing the appropriate refractive correction. The cost of this appointment and of any refractive correction will have to be met by the participant. Anisometropic participants will be encouraged to wear contact lenses as this has been shown to be the best option to minimise aniseikonia (Winn et al., 1988). Participants must be adapted to any refractive correction, having worn the correction for at least four months (Stewart et al., 2004).

Participant type(s)
Patient

Age group
Adult

Sex
Not Specified

Target number of participants
Sample size calculations indicate that the study will be continued until 32 participants have finished in each group.

Key exclusion criteria
1. Personal history of epilepsy.
2. Unilateral amblyopia with visual acuity worse than 6/36 or better than 6/9 in the amblyopic eye and 6/9 or worse in the non-amblyopic eye.
3. Amblyogenic factor: cases where amblyopic eye has less than 1D more hypermetropia or less than 2D more astigmatism than the non-amblyopic eye.
4. Ophthalmoscopically detectable anomalies of fundus or defects of the visual pathway.
5. Patients under 10 years old
6. History of strabismus or other cause of reduced visual acuity (eg cataract) in first two years of life

Date of first enrolment
01/11/2001

Date of final enrolment
31/12/2010

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Institute of Optometry
London

United Kingdom
SE1 6DS

Sponsor information

Organisation
Department of Health

Sponsor details
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.dh.gov.uk/Home/fs/en

Funder(s)

Funder type
Government

Funder Name
City Eye Clinic (EYENET) (UK) NHS R&D Support Funding

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?
Results article	results	01/01/2011		Yes	No