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European Paediatric and Amblyopia Treatment study for Children (EuPATCH): the role of feedback on adherence to amblyopia treatment

Submission date	**Recruitment status**	[X] Prospectively registered
31/07/2013	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
23/08/2013	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
11/06/2020	Eye Diseases	[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Amblyopia (also called lazy eye) is the most common disease affecting vision in childhood. Currently 30% of children treated for amblyopia do not reach normal vision after a year or more of treatment. Poor adherence to patching (wearing an eye patch) and glasses wearing has been identified as a potential contributing factor for this problem. Electronic monitors have been used in various studies. However, at present none of these studies have provided feedback to parents about the results of the measurements. In other diseases feedback about compliance to treatment has been shown to be of benefit. For example, it has been shown that feedback to parents and patients about the frequency of use of steroid inhalers can significantly increase adherence to the daily use of inhaled steroids in children with asthma. The aim of this study will be to investigate whether giving feedback to families about the amount of spectacle and patch wear can improve adherence and in turn the outcome of amblyopia therapy.

Who can participate?
Amblyopic children aged between 2 and 8 years.

What does the study involve?
Children will be randomly allocated to one of two groups: the feedback group and the control group. Both groups will be asked to wear their glasses full time and to patch (10 hours/day, 6 days/week) during a 12-week period. Patients will be examined every 3 weeks. Patients within the feedback group will be given feedback from information provided by the monitors.

What are the possible benefits and risks of participating?
There may be no direct benefit to the patient; however, we anticipate that patients in the study will have shorter waiting times and will be seen more often than the comparative NHS treatment, leading to the possible total treatment time being reduced. The study is likely to have only minimal risk with possible occurrence of side effects similar to the usual clinical treatment, including increase of squint, double vision or reduced vision in the better eye (which is almost always reversible).

Where is the study run from?
University of Leicester (UK).

When is the study starting and how long is it expected to run for?
The study is expected to start in September 2013 and run for about 2 years; recruitment will be during the first 1.5 years of the study.

Who is funding the study?
National Eye Research Centre (NERC), UK

Who is the main contact?
Professor Irene Gottlob
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Contact information

Type(s)
Scientific

Contact name
Prof Irene Gottlob

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
Version 1

Study information

Scientific Title

The effect of feedback to adherence to glasses and patch wear in amblyopia treatment: a randomised clinical trial

Acronym
EuPATCH

Study objectives
The adherence to amblyopia treatment in children receiving feedback about the level of adherence to patching after 720 hours of prescribed patching over 12 weeks will be significantly higher than those who do not receive feedback.

Ethics approval required
Old ethics approval format

Ethics approval(s)
NRES Committee East Midlands - Derby, 15/08/2013, ref: 13/EM/0285

Study design
Unmasked randomised controlled trial

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 the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Amblyopia

Interventions
There will be two treatment arms:
A. Feedback Group: A period of 12 weeks of full-time glasses wearing and patching (10 hrs/day, 6 days/week) followed by feedback on hours of glasses and patch wear at each examination (n=51).
B. Control Group: A period of 12 weeks of full-time glasses wearing and patching (10 hrs/day, 6 days/week) without feedback on hours of glasses and patch wear at each examination (n=51).
The total time the patients will be in the trial is 12 weeks.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Adherence is determined as the the number of hours patched patching over 12 weeks.

Secondary outcome measures
1. Number of hours of glasses wear over the 12 week period.
2. Visual outcome using the formula described by Stewart et al. (% deficit corrected) over the 12 week period

Overall study start date
15/08/2013

Completion date
31/12/2018

Eligibility

Key inclusion criteria
1. Children (age range is between 2-8 years inclusive) with monocular amblyopia (difference of ≥ 0.3 logMAR visual acuity between eyes) due to anisometropia (≥ 1.5D in at least one eye or 1D difference between the two eyes), strabismus or both
2. Previous patching ≤ 18 months

Participant type(s)
Patient

Age group
Child

Lower age limit
2 Years

Upper age limit
8 Years

Sex
Both

Target number of participants
102

Key exclusion criteria
Children with other ophthalmic or neurological diseases, bilateral amblyopia or premature children.

Date of first enrolment
01/10/2013

Date of final enrolment
31/12/2017

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
University of Leicester
Leicester
United Kingdom
LE2 7LX

Sponsor information

Organisation
University of Leicester (UK)

Sponsor details
College of Medicine
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Sponsor type
University/education

ROR
https://ror.org/04h699437

Funder(s)

Funder type
Charity

Funder Name
National Eye Research Centre (NERC) (UK)

Alternative Name(s)
National Eye Research Centre, SightResearchUK, SRUK, NERC

Funding Body Type
Private sector organisation

Funding Body Subtype
Universities (academic only)

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer reviewed journal.

Intention to publish date
01/12/2020

Individual participant data (IPD) sharing plan
The data sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No