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Personalising Dosing Strategy for Amblyopia Treatment

Submission date
17/12/2013

Recruitment status
No longer recruiting

Registration date
17/12/2013

Overall study status
Completed

Last Edited
25/06/2020

Condition category
Eye Diseases

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims
Amblyopia is reduced vision of one eye associated with a squint (misalignment of one eye) or anisometropia (one eye not in focus) occuring during the normal period of visual development (before 7 years of age). The mainstay treatment is full-time spectacle wear followed by patching of the good eye (covering the good eye with a patch like a plaster). The main objective of this study is to compare a personalised dosing strategy with a standardised dosing strategy of patching treatment for children with amblyopia.

Who can participate?
Participants need to be between 3 and 8 years of age with amblyopia associated with a squint and/or anisometropia.

What does the study involve?
There are three stages to the study. Firstly, an initial assessment will make sure that the patient's vision is stable and the diagnosis is correct. Secondly, those needing glasses will enter the 'refractive adaptation phase' and wear glasses full-time for 18 weeks. Thirdly, those who still have amblyopia after refractive adaptation will be randomly allocated to receive patching either with a personalised dosing strategy (PDS) or a standardised dosing strategy (SDS). Those prescribed the PDS will have their patient characteristics, age, type of amblyopia and severity of amblyopia entered into the PDS software and a prescribed duration of patching will be calculated. Those in the SDS group will be prescribed 2 hours a day of patching if they have mild amblyopia, 3 hours a day if they have moderate amblyopia and 5 hours a day if they have severe amblyopia. The actual duration of patching will be monitored using an occlusion dose monitor.

What are the possible benefits and risks of participanting?
The participants will have increased monitoring follow-up visits every 2 weeks. There are no side effects of the treatment.

Where is the study run from?
The study will be run at Princess Alexander Hospital, Harlow and Hillingdon NHS Trust (UK).

When is the study starting and how long is it expected to run for?
The study started recruiting in September 2013 and will continue recruiting until November 2014 and follow-up until mid 2015.

Who is funding the study?
National Institute of Health Research (UK).

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
15042

Study information

Scientific Title
Randomised trial of a personalised dosing strategy versus a standardised dosing strategy for childhood amblyopia

Study objectives
Amblyopia is the most common visual disorder of childhood in the Western world with an estimated prevalence of between 2-5%, accounting for approximately 90% of NHS Children's Eye Service. Most commonly, one eye is affected and the amblyopia - that is, a loss of vision - arises because of a squint (misalignment of the eyes) or anisometropia (two eyes focus differently). Amblyopia is considered treatable, and the importance of doing so has been highlighted by findings of an increased lifetime risk of blindness arising from disease or injury to the 'good eye' and statutory occupational exclusion.

However, it is acknowledged that amblyopia therapy (typically a patch over the good eye to promote function in the affected eye) is inefficient, and for most children the deficit is not fully

corrected. Treatment regimens range from a few minutes a day to all waking hours and are decided mainly on an ad hoc rather than rational basis. These approaches all constitute 'standardised dosing strategies' (SDS) and do not accord with a growing realisation in medicine that treatment is best tailored to the individual: the so-called 'personalised dosing strategy' approach (PDS). Our proposed study seeks to evaluate the PDS approach by conducting a randomised trial comparing SDS with PDS in children with amblyopia aged 3 to 8 years. This study comprises three phases: 'initial assessment', 'refractive adaptation' and 'occlusion'. Children will be randomised to receive SDS or PDS occlusion once they have completed the refractive adaptation phase.

If a PDS approach were shown to be practical and potentially superior to the SDS approach it would be a highly significant advance in the management of the condition: the amount and duration of treatment could be minimised with clear benefits to the patient and with a potential gain in cost-effectiveness.

Hypothesis: a personalised dosing strategy provides superior visual outcome and a shorter treatment period than a standardised dosing strategy

More details can be found at: http://public.ukcrn.org.uk/search/StudyDetail.aspx?StudyID=15042

Ethics approval required
Old ethics approval format

Ethics approval(s)
Bloomsbury Ethics board, first MREC approval date 07/08/2013, 13/LO/0773

Study design
Randomised interventional treatment trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Topic: Eye, Generic Health Relevance and Cross Cutting Themes; Subtopic: Eye (all Subtopics), Generic Health Relevance (all Subtopics); Disease: Ophthalmology, Paediatrics

Interventions
Once participants enter the occlusion phases they are randomised to receive a Personalised Dosing Strategy (PDS) or a Standardised Dosing Strategy (SDS) of occlusion by patching. Those assigned PDS will have their patient characteristics, age, type of amblyopia and severity of amblyopia entered into the PDS software and their dose will be calculated. The actual dose recieved will be monitored using an occlusion dose monitor (a small data logger recording when patch is on and off the eye to the nearest second). Dosing will be modified at each follow-up visit depending on compliance with occlusion.

Those assigned the Standard Dosing Strategy will be prescribed 2 hours a day if they have mild, 3 hours if they have moderate and 5 hours a day if they have severe amblyopia. The occlusion they actually recieve will be monitored using an occlusion dose monitor.

Occlusion, Occlude eye by patching. Monitor dose worn with occlusion dosed monitor.
Refractive adaptation, Full-time glasses wear for 18 weeks monitored 6-weekly;
Follow Up Length: 12 month(s)

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
Visual acuity change; Timepoint(s): Change in visual acuity of the amblyopic eye during treatment

Key secondary outcome(s))
The secondary outcome measure will be stereoacuity measured using the Frisby test and the Randot pre-schooler test

Completion date
01/03/2015

Eligibility

Key inclusion criteria
1. The trial will recruit subjects with amblyopia associated with:
1.1. Strabismus
1.2. Anisometropia
1.3. A combination of anisometropia and strabismus
2. Children aged between 3 and 8 years with visual acuity of 0.2 logMAR or lower in the worst eye and an inter-ocular difference of at least 0.2 log units with the presence of anisometropia and/or strabismus and no other ocular pathology including amblyopia associated with form deprivation or previous occlusion treatment history will be eligible for recruitment.
3. Target Gender: Male & Female

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Child

Lower age limit
3 years

Upper age limit
8 years

Sex
All

Key exclusion criteria
1. Those with other ocular pathology
2. Those with form deprivation amblyopia as this is a minority group and often is linked with other ocular pathology
3. Previous history of treatment for amblyopia
4. Those with learning difficulties and therefore cannot perform an accurate visual acuity test on every occasion tested

Date of first enrolment
01/09/2013

Date of final enrolment
01/11/2014

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
City Community and Health Sciences
London
United Kingdom
EC1V 0HB

Sponsor information

Organisation
City University London (UK)

ROR
https://ror.org/04489at23

Funder(s)

Funder type
Government

Funder Name

NIHR Research for Patient Benefit (RfPB) (UK) Grant Codes: PB-PG-0808-16087

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?
Protocol article	protocol	25/04/2015		Yes	No
HRA research summary			28/06/2023	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes