ISRCTN51712593 https://doi.org/10.1186/ISRCTN51712593

EuPatch (European Paediatric Amblyopia Treatment Study for Children): the role of glasses wearing in amblyopia treatment

Submission date
06/06/2013

Recruitment status
No longer recruiting

Registration date
26/06/2013

Overall study status
Completed

Last Edited
07/05/2024

Condition category
Eye Diseases

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

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. Amblyopia is usually treated with glasses wearing and by patching the better eye (wearing an eye patch). There is controversy whether a long period of glasses wearing before patching, called refractive adaptation, helps in treating children with amblyopia. The aim of this study is to perform a trial to test whether refractive adaptation before patching improves the number of successfully treated children with amblyopia.

Who can participate?
Amblyopic children between 3 and 8 years of age

What does the study involve?
Participants are randomly allocated to one of two groups. One group wears glasses for 18 weeks before patching for amblyopia is started, whereas the other group wears the glasses for 3 weeks before patching.

What are the possible benefits and risks of participating?
The participants receive information material for parents, teachers and children about amblyopia. Decorated patches are given to the children. The waiting time for appointments is likely to be shorter. It could be that the total treatment time is reduced. Possible occurrence of side effects is very similar to the usual clinical treatment and could be rarely increase of squint, double vision or reduced vision in the better eye (which is almost always reversible).

Where is the study run from?
1. University of Leicester (UK)
2. Moorfields Eye Hospital (UK)
3. University of Graz (Austria)
4. University of Heidelberg (Germany)

When is the study starting and how long is it expected to run for?
June 2013 to February 2021

Who is funding the study?
Action Medical Research (UK)

Who is the main contact?
Prof. Irene Gottlob
ig15@le.ac.uk

Contact information

Type(s)
Scientific

Contact name
Prof Irene Gottlob

Contact details
Professor Irene Gottlob (MD, Univ. Doz., FRCOphth)
Professor of Ophthalmology
Ophthalmology Group
University of Leicester
Leicester Royal Infirmary
PO Box 65
Leicester
United Kingdom
LE2 7LX

Additional identifiers

Protocol serial number
120878

Study information

Scientific Title
The role of glasses wearing in amblyopia treatment: a randomised controlled multicentre trial

Acronym
EuPatch

Study objectives
The number of children successfully treated after 720 hours of prescribed patching over 12 weeks is significantly higher following an initial period of 18 weeks glasses wearing period than 3 weeks glasses wearing period prior to patching therapy.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Derby NRES Committee East Midlands, 28/03/2013, ref: 120878

Primary study design
Interventional

Study design
Unmasked randomized controlled trial

Study type(s)
Treatment

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

Interventions
There are two study arms:
Refractive Adaptation Group (n=173): A period of 18 weeks glasses wearing (i.e. RA) will be followed by a period of 24 weeks combined patching (10hrs/day, 6 days/week) and glasses wearing.

Early Patching Group (n=173): A period of 3 weeks glasses wearing will be followed by a period of 24 weeks combined patching (10hrs/day, 6 days/week) and glasses wearing.

Participants will have an initial full ophthalmologist examination including cycloplegic refraction and will be examined subsequently at 6 weekly intervals with visual acuity measurements.

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
Number of children successfully treated after 720 hours of prescribed patching over 12 weeks following an initial period of either 3 weeks or 18 weeks glasses wearing prior to patching therapy

Key secondary outcome(s)
1. To compare the number of patients successfully resolved in ≤ 1080 hours of prescribed patching over 18 weeks, and in ≤ 1440 hours over 24 weeks. Where possible we will also compare the two groups in terms of final visual outcome, total duration of treatment and total amount of patching required
2. To estimate the levels of compliance to glasses and patch wearing
3. To explore the relationship between duration of glasses wearing and patching and improvement in vision
4. To explore whether anisometropes respond better to RA compared to strabismus/mixed patients.
5. To explore whether electronic monitoring influences compliance and visual outcomes
6. Ascertain opinions from carers and children about the study treatment study through a questionnaire given during and on completion of the study

Completion date
14/02/2021

Eligibility

Key inclusion criteria
1. Children (aged 3 to 8 years) with newly detected amblyopia (difference of ≥ 0.3 LogMAR visual acuity between eyes)
2. A clinically significant refractive error (≥ 1.5D in at least 1 eye or 1D difference between the two eyes)
3. Able to perform the visual acuity test

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Child

Lower age limit
3 Years

Upper age limit
8 Years

Sex
All

Total final enrolment
341

Key exclusion criteria
1. Children without amblyopia as defined above or with amblyopia as defined above but with other ophthalmic or neurological diseases, or premature children
2. Bilateral amblyopia (vision of better eye corrected visual acuity > 0.2 LogMAR) is also an exclusion criterion

Date of first enrolment
20/06/2013

Date of final enrolment
12/03/2020

Locations

Countries of recruitment
United Kingdom

England

Austria

Germany

Greece

Switzerland

Study participating centre
Leicester Royal Infirmary
Leicester
United Kingdom
LE2 7LX

Sponsor information

Organisation
University of Leicester (UK)

ROR
https://ror.org/04h699437

Funder(s)

Funder type
Charity

Funder Name
Action Medical Research (UK)

Alternative Name(s)
action medical research for children, actionmedres, The National Fund for Research into Crippling Diseases, AMR

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
Data will be available for sharing upon request

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		04/05/2024	07/05/2024	Yes	No
Protocol file	version 2	17/01/2014	05/06/2023	No	No