

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	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 26/06/2013	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 07/05/2024	Condition category Eye Diseases	<input type="checkbox"/> 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
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Contact information

Type(s)
Scientific

Contact name
Prof Irene Gottlob

Contact details
Professor Irene Gottlob (MD, Univ. Doz., FRCOphth)
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Study design

Unmasked randomized 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 to request a patient information sheet

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 measure

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

Secondary outcome measures

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

Overall study start date

17/06/2013

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 ($\geq 1.5D$ in at least 1 eye or 1D difference between the two eyes)
3. Able to perform the visual acuity test

Participant type(s)

Patient

Age group

Child

Lower age limit

3 Years

Upper age limit

8 Years

Sex

Both

Target number of participants

346

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

Austria

England

Germany

Greece

Switzerland

United Kingdom

Study participating centre

Leicester Royal Infirmary

Leicester

United Kingdom

LE2 7LX

Sponsor information

Organisation

University of Leicester (UK)

Sponsor details

College of Medicine

Biological Sciences and Psychology

Level 4, MSB
Leicester
England
United Kingdom
LE1 7RH

Sponsor type

University/education

Website

<http://www.le.ac.uk/>

ROR

<https://ror.org/04h699437>

Funder(s)

Funder type

Charity

Funder Name

Action Medical Research (UK)

Alternative Name(s)

actionmedres, action medical research for children, AMR

Funding Body Type

Private sector organisation

Funding Body Subtype

Trusts, charities, foundations (both public and private)

Location

United Kingdom

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date

01/08/2023

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?
Protocol file	version 2	17/01/2014	05/06/2023	No	No
Results article		04/05/2024	07/05/2024	Yes	No