Electronic Recording of Compliance with Patching Therapy for Amblyopia.

Submission date	Recruitment status No longer recruiting	Prospectively registered		
20/12/2005		☐ Protocol		
Registration date	Overall study status Completed	Statistical analysis plan		
20/12/2005		[X] Results		
Last Edited	Condition category	Individual participant data		
10/06/2021	Eye Diseases			

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Dr S.E. Loudon

Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N/A

Study information

Scientific Title

Electronic Recording of Compliance with Patching Therapy for Amblyopia.

Acronym

ERPAG

Study objectives

Compliance with patching therapy for amblyopia can be improved by an educational programme aimed primarily at the child.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics approval received from the local medical ethics committee

Study design

Multicentre, randomised, single blinded, placebo controlled, parallel group trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Not specified

Study type(s)

Treatment

Participant information sheet

Health condition(s) or problem(s) studied

Amblyopia

Interventions

Children in the intervention group received the educational cartoon story together with a calendar and reward stickers and a one-page information sheet for the parents. The cartoon was designed as a picture story, without text and was designed from a childs perspective.

Scientific contact: Prof. H.J. Simonsz, simonsz@compuserve.com.

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

Percentage of compliance (realised/prescribed occlusion time) in the intervention and control group.

Secondary outcome measures

Secondary outcome measure was influence of social-economic, ethnic and clinical factors on compliance.

Overall study start date

01/07/2001

Completion date

31/12/2005

Eligibility

Key inclusion criteria

- 1. All newly diagnosed amblyopic children with an inter-ocular difference in visual acuity of at least 0.2 logMAR, strabismus and/or an anisometropia or a deprivation (e.g. cataract).
- 2. Both genders
- 3. No age limitation

Participant type(s)

Patient

Age group

Child

Sex

Not Specified

Target number of participants

300

Total final enrolment

149

Key exclusion criteria

Previous treatment for amblyopia, neurological disorder, medication, other eye disorder, decreased visual acuity caused by brain damage or trauma

Date of first enrolment

01/07/2001

Date of final enrolment

31/12/2005

Locations

Countries of recruitment

Netherlands

Study participating centre
Erasmus Medical Center Rotterdam,
Rotterdam
Netherlands
3015 GD

Sponsor information

Organisation

Erasmus Medical Center (The Netherlands)

Sponsor details

Department of Ophthalmology Dr. Molewaterplein 50 Rotterdam Netherlands 3015 GD

Sponsor type

Hospital/treatment centre

ROR

https://ror.org/018906e22

Funder(s)

Funder type

Research organisation

Funder Name

The Netherlands Organization for Health Research and Development (ZonMw) (The Netherlands)

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		01/11/2009	10/06/2021	Yes	No