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Electronic Recording of Compliance with Patching Therapy for Amblyopia.

Submission date	Recruitment status	[_] Prospectively registered
20/12/2005	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
20/12/2005	Completed	[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
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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
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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