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Implementation of Compliance Improvement for Amblyopia Prevention

Submission date	Recruitment status	[_] Prospectively registered
26/09/2006	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
26/09/2006	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
05/04/2012	Eye Diseases	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Implementation of Compliance Improvement for Amblyopia Prevention: further training course about compliance, an effective information programme and direct referral by child health care centres, primary with orthoptists in foreign and low-SES (socio-economic status) neighbourhoods

Acronym
ICI-AP

Study objectives
Orthoptists work more effectually by using an improved compliance enhanced programme and a training course on compliance.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval received from the local medical ethics committee

Study design
Non-randomised, paralled armed trial

Primary study design
Interventional

Secondary study design
Non randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

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

Interventions
At end of year one the orthoptist will receive a three-days training course on compliance with amblyopia prevention. Strategies and techniques to reduce non-compliance are given during the training.

All children included in the first year are the control group: receive standard orthoptic care.

All children included in the second year is the intervention group: receive the improved educational cartoon story together with a calendar and reward stickers, and a one-page information sheet for the parents. The cartoon is designed as a picture story, without text and is designed from a childs perspective.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Whether the orthoptists work is effectual, based on measurements (i.e. questionnaires) at the start of the study, before and after the training course, and at the end of the second year.

Secondary outcome measures
The electronic occlusion measurements for compliance (actual occlusion time/prescribed occlusion time), the fraction realised Child Health Care centre referrals and the overall acuity improvement will be determined.

Overall study start date
01/05/2006

Completion date
01/05/2009

Eligibility

Key inclusion criteria
1. All newly diagnosed children with an inter-ocular difference in visual acuity of more than two logarithm of the Minimum Angle of Resolution (logMAR), strabismus and/or an anisometropia or a deprivation (e.g. cataract)
2. Age: three to six years
3. Both genders
4. Children living in an area with low Socio-Economic Status (SES) in the four big cities of the Netherlands

Participant type(s)
Patient

Age group
Child

Lower age limit
3 Years

Upper age limit
6 Years

Sex
Both

Target number of participants
300

Key exclusion criteria
1. Children with equal visual acuity between the eyes (less than one logMAR line of difference in visual acuity between eyes)
2. Previous treatment for amblyopia, neurological disorder, medication, other eye disorder or decreased visual acuity caused by brain damage or trauma

Date of first enrolment
01/05/2006

Date of final enrolment
01/05/2009

Locations

Countries of recruitment
Netherlands

Study participating centre
Erasmus Medical Center Rotterdam
Rotterdam
Netherlands
3000 CA

Sponsor information

Organisation
Erasmus Medical Center (The Netherlands)

Sponsor details
P.O. Box 2040
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3000 CA

Sponsor type
Hospital/treatment centre

Website
http://www.erasmusmc.nl/content/englishindex.htm

ROR
https://ror.org/018906e22

Funder(s)

Funder type
Research organisation

Funder Name
The Netherlands Organisation for Health Research and Development (Zon-MW) (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	results	01/12/2010		Yes	No
Results article	results	01/12/2011		Yes	No