

Implementation of Compliance Improvement for Amblyopia Prevention

Submission date 26/09/2006	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 26/09/2006	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 05/04/2012	Condition category Eye Diseases	<input type="checkbox"/> Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr H J Simonsz

Contact details
Erasmus Medical Center Rotterdam
Department of Ophthalmology
Room Ba 104
P.O. Box 2040
Rotterdam
Netherlands
3000 CA
+31 (0)10 408 7275/7276
simonsz@compuserve.com

Additional identifiers

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

Primary study design

Interventional

Study design

Non-randomised, paralld armed trial

Study type(s)

Treatment

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(s)

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.

Key secondary outcome(s)

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.

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

Healthy volunteers allowed

No

Age group

Child

Lower age limit

3 Years

Upper age limit

6 Years

Sex

All

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)

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

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