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Pharmacologic versus Optical Penalisation in the treatment of Amblyopia

Submission date 22/09/2007	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 10/10/2007	**Overall study status** Completed	
Last Edited 23/05/2019	**Condition category** 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
04/0643

Study information

Scientific Title
Pharmacologic versus Optical Penalisation in the treatment of Amblyopia

Acronym
POPA

Study objectives
Amblyopia may be differentially treated with pharmacologic and optical penalisation.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics Committee of Hospital Ramon y Cajal approved the study on the 15th June 2007 (ref: PI 04 /0643).

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

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

Interventions
70 children 2 to 10 years of age are randomised to atropine or optical penalisation for the treatment of amblyopia.

1% atropine (Colircusi Atropina 1%, AlconCusi, Barcelona, Spain) will be prescribed twice a week when interocular acuity difference is present, and once a week for maintenance therapy (equal visual acuity in both eyes) until the next follow-up visit. Atropine will be withdrawn when visual acuity remains equal in the amblyopic and sound eye in two consecutive follow-up visits, but monitoring without treatment will continue. Atropine will be discontinued when allergy or intolerance occurs, and when reverse amblyopia is suspected. Sunglasses will be used at discretion of the child and family. Atropine will be interrupted within one week before follow-up examination, to measure visual acuity and maintain some cycloplegic effect, and the ability to monitor compliance by dynamic retinoscopy.

Optical penalisation will be achieved by positive defocus of the sound eye (overplus glass). Using a vectographic projector showing the 20/50 letter at a distance where the amblyopic eye can read it, the patient wears polaroid glasses over best correction in a trial frame. Sphere is added to the sound eye until the patient can read only letters seen by the amblyopic eye. We will use the minimal amount of defocus necessary, checked by fixation switch to the amblyopic eye at distance using this control (in children with strabismic deviation vectographic control is not necessary). Optical penalisation will be carefully checked and readjusted if necessary in every follow-up visit. Defocus will be discontinued when visual acuity remains equal in the amblyopic and sound eye for two consecutive visits, and visual acuity will continue to be monitored.

Follow-up will be scheduled with intervals of 2 - 6 months, depending on the severity of amblyopia and response to treatment. At least two follow-up visits will be required during the 6 month period of the study. The outcome measures will be determined at 6 months (i.e., after 6 months of treatment).

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Atropine

Primary outcome measure
Lines of improvement of visual acuity of the amblyopic eye at 6 months.

Secondary outcome measures
Stereoacuity measurement at 6 months.

Overall study start date
01/11/2007

Completion date
01/10/2008

Eligibility

Key inclusion criteria
1. Aged 2 - 10 years
2. Ability to cooperate with measurement of visual acuity by the logarithmic Minimal Angle Resolution (logMAR) crowded test with at least 2 logMAR lines of difference in visual acuity between the two eyes

Participant type(s)
Patient

Age group
Child

Lower age limit
2 Years

Upper age limit
10 Years

Sex
Both

Target number of participants
35 in each group (total 70)

Total final enrolment
70

Key exclusion criteria
1. Previous amblyopia treatment
2. Previous eye surgery
3. Ocular disease

Date of first enrolment
01/11/2007

Date of final enrolment
01/10/2008

Locations

Countries of recruitment
Spain

Study participating centre
Ctra Colmenar km 9100
Madrid
Spain
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Sponsor information

Organisation
Hospital Ramon y Cajal (Spain)

Sponsor details
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Sponsor type
Hospital/treatment centre

Website
http://www.hrc.es/

ROR
https://ror.org/050eq1942

Funder(s)

Funder type
Government

Funder Name
Research Funding Agency of the Spanish Ministry of Health (Fondo de Investigacion Sanitaria [FIS]) (Spain) (ref: 040643)

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	01/03/2008	23/05/2019	Yes	No