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Rehabilitation of poor vision of neurological origin

Submission date
16/02/2012

Recruitment status
No longer recruiting

Registration date
27/02/2012

Overall study status
Completed

Last Edited
08/12/2015

Condition category
Ear, Nose and Throat

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims
Visual impairment is a decreased ability to see to a degree that causes problems not fixable by usual means, such as glasses. There are about 180 million visually impaired people in the world. Visual impairment can be caused by defects in the eye or neurological problems in the nerves that carry information from the eye to the brain, where visual images are interpreted. The aim of this study is to test a new method of rehabilitation for low or poor vision.

Who can participate?
Patients with poor vision of neurological origin, aged over 18, living in Colombia, South America.

What does the study involve?
The study involves a new method of rehabilitation based on covering the healthy eye (i.e., the eye with better vision) and stimulating the eye with poor vision for periods of 5 hours daily for 10 days. The intensive stimulation is applied through a computer program and involves different kinds of stimuli, including discrimination of contrast and color, interpreting complex shapes, reading paragraphs with different font sizes, and perception of motion, speed and contour.

What are the possible benefits and risks of participating?
The potential benefit would be some degree of recovery of vision.

Where is the study run from?
Neurological Institute of Colombia.

When is the study starting and how long is it expected to run for?
June 2010 to June 2012.

Who is funding the study?
Neurological Institute of Colombia.

Who is the main contact?
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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
Visual rehabilitation: brain plasticity or neuronal regeneration?

Study objectives
A 78 years old man presented an ischemic optic neuropathy of the right eye, leaving him with a vision of 20/200; this low vision remain stable for 6 years when he repeated ischemic optic neuropathy in the left eye, also producing low vision in that eye; the right eye, the affected first, recovered a lo of the loss of vision in the course of 2 or 3 months.

Based on this observation we elaborate the hypothesis for this research which consists of a rehabilitation therapy based on the occlusion of the healthy eye or the eye with better vision for 5 hours daily for 2 weeks and submit the affected eye to an intensive optical functional occlusion therapy (OOF).

Ethics approval required
Old ethics approval format

Ethics approval(s)
Neurological Institute of Colombia Ethics Committee, 09/03/2009

Study design
Quasi-experimental clinical trial with intervention

Primary study design
Interventional

Secondary study design
Cohort study

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Low vision

Interventions
Patients who meet the criteria for inclusion and exclusion are intervened with occlusion of the normal or better eye and an intensive visual stimulation procedure for periods of 5 hours daily for 10 days. The intensive visual stimulation is applied through a computer program, with stimuli of different kinds, such as discrimination of contrast, color vision, interpretation of complex shapes, reading paragraphs with different font sizes, perception of motion, speed and contour etc. fMRI and visual evoked potentials are also performed. All this test are realized before and after intervention

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Comparison of tests before and after intervention will permit the evalution of the results

Secondary outcome measures
Changes in activation of cortical visual areas by functional magnetic resonance

Overall study start date
30/06/2010

Completion date
30/06/2012

Eligibility

Key inclusion criteria
1. Age greater than or equal to 18
2. Isquemic optic neuropathy
3. Optic neuropathy by Multiple Sclerosis
4. Amblyopia secondary to strabismus
5. Traumatic optic neuropathy
6. At least one year of evolution of the previous conditions
7. Alteration of unilateral or bilateral visual acuity, defined as unilateral or bilateral visual acuity less than 20/60
8. In case of bilateral involvement, there should be an eye with better visual acuity, still below the 20/60
9. The visually impaired should have some stability over time, without clinical signs of improvement, even with the best possible optical correction or intervention
10. Clinical condition equivalent to a diagnosis of low vision

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
30

Key exclusion criteria
1. Visual deficit bilaterally and in the same visual range
2. Optic Atrophy of nonspecific of uncertain origin
3. Optical refractive errors
4. Low vision of ophthalmic pathology: glaucoma, sequelae of retinopathy of prematurity, hypertensive retinopathy, diabetic retinopathy, cataract, retinitis pigmentosa and macular degeneration associated with age
5. Presence of tumor disease of the optic nerve
6. Intensive therapy with steroids in the last 6 months
7. Relapsed Acute optic neuritis type in the last 6 months
8. Lack of ability to understand instructions and adhere to intervention

Date of first enrolment
30/06/2010

Date of final enrolment
30/06/2012

Locations

Countries of recruitment
Colombia

Study participating centre
Neurological Institute of Colombia
Medellin
Colombia
-

Sponsor information

Organisation
Neurological Institute of Colombia (Colombia)

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Sponsor type
Research organisation

Website
http://www.neurologico.org.co

ROR
https://ror.org/00fsjhf77

Funder(s)

Funder type
Research organisation

Funder Name
Neurological Institute of Colombia, Medellín (Colombia)

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