

Rehabilitation of poor vision of neurological origin

Submission date 16/02/2012	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 27/02/2012	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 08/12/2015	Condition category Ear, Nose and Throat	<input type="checkbox"/> Individual participant data <input type="checkbox"/> 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?

José Iván Jiménez

direccion@neurologico.org.co

Contact information

Type(s)

Scientific

Contact name

Dr Jose Ivan Jimenez

Contact details

Neurological Institute of Colombia

Calle 55 No. 46-36

Medellin

Colombia

-

+57 4 5718178

direccion@neurologico.org.co

Additional identifiers

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

Study type(s)

Treatment

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(s)

Comparison of tests before and after intervention will permit the evaluation of the results

Key secondary outcome(s)

Changes in activation of cortical visual areas by functional magnetic resonance

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

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)

ROR

<https://ror.org/00fsjhf77>

Funder(s)

Funder type

Research organisation

Funder Name

Neurological Institute of Colombia, Medellín (Colombia)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration