# Rehabilitation of poor vision of neurological origin

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

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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

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# Sponsor information

### Organisation

Neurological Institute of Colombia (Colombia)

### Sponsor details

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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