ISRCTN31408782 https://doi.org/10.1186/ISRCTN31408782

# Paralysis post stroke, rehabilitation therapy by immobilizing the normal upper arm

| Submission date | Recruitment status | [ ] Prospectively registered |
|---|---|---|
| 05/03/2012 | No longer recruiting | [ ] Protocol |
| **Registration date** | **Overall study status** | [ ] Statistical analysis plan |
| 13/03/2012 | Completed | [ ] Results |
| **Last Edited** | **Condition category** | [ ] Individual participant data |
| 10/09/2014 | Circulatory System | [ ] Record updated in last year |

## Plain English summary of protocol

Background and study aims
A stroke is the result of damage to the blood circulation of the brain, often causing paralysis of the arm and leg of one side of the body. Recovery from this paralysis is difficult and can take months or years, with poor results especially in the recovery of a paralyzed hand. In recent years a new rehabilitation method has been used which involves immobilizing the healthy upper limb and subjecting the paralyzed upper limb to a process of intensive rehabilitation for 5 hours daily for 10 days, with surprisingly good results in terms of recovery of movement in the affected upper limb.

Who can participate?
People of any age with paralysis caused by a stroke, at least one year after the stroke, who retain at least traces of movement in the affected hand.

What does the study involve?
The rehabilitation procedure used with patients involves immobilization of the upper healthy limb by a device specially designed to prevent movement of this limb especially the hand, and subjecting the affected limb to perform movements of daily living such as lifting a glass of water to their mouths, touching the head, and picking up small objects with the fingers. The movements of the affected limb are evaluated before and after the rehabilitation.

What are the possible benefits and risks of participating?
The potential benefit of this treatment is improved movement of the affected limb. There are no risks involved with this treatment.

Where is the study run from?
This study will be performed in the service of neurorehabilitation of the Neurological Institute of Colombia in Medellin, Republic of Colombia.

When is the study starting and how long is it expected to run for?
The study ran from July 2009 to December 2012.

Who is funding the study?
The study is funded by the Neurological Institute of Colombia.

Who is the main contact?
Jose Ivan Jimenez
direccion@neurologico.org.co

# Contact information

### Type(s)
Scientific

### Contact name
Dr Jose Ivan Jimenez

### Contact details
Calle 55 No. 46-36
Medellin
Colombia
-
+57 (0) 4 5718178
direccion@neurologico.org.co

# Additional identifiers

### EudraCT/CTIS number

### IRAS number

### ClinicalTrials.gov number

### Secondary identifying numbers
N/A

# Study information

### Scientific Title
Motor rehabilitation: brain plasticity or neuronal regeneration?

### Study objectives
The effectiveness of motor rehabilitation by means of constraint-induced therapy following a stroke has been clearly established by the publication of several research papers. Constraint-induced therapy involves restricting the motility of the healthy upper limb and forcing the affected upper limb for 5 hours daily for 10 days to perform exercises described as movements of everyday life.

On the other hand, the explanations of the change that occur in the central nervous system with intensive constraint therapy have not been investigated properly and there are various theories such as brain plasticity is responsible for the improvement of motility.

Hypothesis:
Improvement that occurs with constraint-induced therapy is caused by regeneration of the corticospinal or pyramidal neurons. We intend to test the validity of this hypothesis that contradicts the dogma of non-regeneration of neurons.

## Ethics approval required
Old ethics approval format

## Ethics approval(s)
Ethics Committee of the Neurological Institute of Colombia, 17/02/2009

## Study design
Quasi-experimental clinical trial

## Primary study design
Interventional

## Secondary study design
Non randomised controlled trial

## 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
Stroke motor deficit

## Interventions
Patients who meet inclusion criteria will undergo physical rehabilitation therapy consisting of immobilizing the upper healthy limb by means of a specially designed vest and forcing the affected upper limb to perform movements described as the movements of everyday life, such as lifting a glass of water, touching an ear, scratching the head, picking up small objects with the fingers, etc.

This therapy will be for 5 hours daily Monday through Friday for two weeks; the rest of the day the patient will continue with his good arm immobilized. The immobilization of the arm should be removed at night. During this therapy a physiotherapist will be all the time forcing the patient to perform the movements ordered.

## Intervention Type
Other

## Phase
Not Applicable

### Primary outcome measure
1. Before and after constriction-induced therapy, the movement of the arm of patient are measured, taking into account the angle of movement at the level of fingers, wrist, elbow and shoulder, and also assessing the strength of these movements.
2. The movements of the arm and gait of the patient will be filmed before and after the therapy. Furthermore, patients will undergo a functional magnetic resonance imaging (fMRI) scan before and after the therapy.

The comparison of the above parameters before and after treatment will measure the effectiveness of treatment.

### Secondary outcome measures
Changes in motor cortex activity, assessed by fMRI, allow evaluation of the role of the cortical areas in the rehabilitation of the motor function by the therapy

### Overall study start date
30/06/2010

### Completion date
30/06/2012

## Eligibility

### Key inclusion criteria
1. Patients of either gender without age limits
2. Presence of motor deficits due for stroke with hemiparesis or monoparesis
3. At least 3 years after the stroke
4. The affected arm should have at least traces of movement

### Participant type(s)
Patient

### Age group
Adult

### Sex
Both

### Target number of participants
40

### Key exclusion criteria
1. Presence of joint contractures
2. Lower motor neuron pathology
3. Pathology that compromises the neuromuscular junction
4. Spinal cord pathology
5. Inability to understand instructions and adhere to the intervention

### Date of first enrolment
30/06/2010

**Date of final enrolment**
30/06/2012

# Locations

**Countries of recruitment**
Colombia

**Study participating centre**
**Calle 55 No. 46-36**
Medellin
Colombia
-

# Sponsor information

**Organisation**
Neurological Institute of Colombia (Colombia)

**Sponsor details**
Calle 55 No. 46-36
Medellin
Colombia
-
+57 (0) 4 5718178
direccion@neurologico.org.co

**Sponsor type**
Hospital/treatment centre

**ROR**
https://ror.org/00fsjhf77

# Funder(s)

**Funder type**
Hospital/treatment centre

**Funder Name**
Neurological Institute of Colombia (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