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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?
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Contact information

Type(s)
Scientific

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Additional identifiers

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

Primary study design
Interventional

Study design
Quasi-experimental clinical trial

Study type(s)
Treatment

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(s)
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.

Key secondary outcome(s)
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

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

Healthy volunteers allowed
No

Age group
Adult

Sex
All

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
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Sponsor information

Organisation
Neurological Institute of Colombia (Colombia)

ROR
https://ror.org/00fsjhf77

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Neurological Institute of Colombia (Colombia)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration