

# Sertraline in post Stroke Depression in Irkutsk, Russia

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| <b>Submission date</b><br>27/02/2012   | <b>Recruitment status</b><br>No longer recruiting | <input type="checkbox"/> Prospectively registered<br><input type="checkbox"/> Protocol                       |
| <b>Registration date</b><br>30/03/2012 | <b>Overall study status</b><br>Completed          | <input type="checkbox"/> Statistical analysis plan<br><input type="checkbox"/> Results                       |
| <b>Last Edited</b><br>18/09/2014       | <b>Condition category</b><br>Circulatory System   | <input type="checkbox"/> Individual participant data<br><input type="checkbox"/> Record updated in last year |

## Plain English summary of protocol

### Background and study aims

The current treatment of stroke focuses on early diagnosis and early use of medication that improves the disease. However, a major proportion of patients has remaining disability and still needs rehabilitation. Depression after ischemic stroke is one of the major problems complicating the rehabilitation. A major challenge is therefore to help patients maintain self-management strategies introduced in the rehabilitation period, and thereby enhance a longer lasting effect of rehabilitation.

Goal planning or goal setting is considered an important part of stimulation techniques in rehabilitation. Several studies show that goal planning can influence patients' adherence to treatment regimes and improve immediate patient performance, but evidence regarding how it may improve results after rehabilitation programs is inconsistent. Rehabilitation goals often address motor recovery not mental and behavioral elements. A new and potentially more effective rehabilitation program has been developed. The main aim of this study is to measure the usefulness of this new rehabilitation program compared to the current traditional rehabilitation programs. The expected usefulness of the new program will be expressed in terms of goal attainment and health benefits for participating patients, and with regard to if it helps with the recovery process.

### Who can participate?

Patients who are admitted to the clinic of nervous diseases with cerebral ischemic stroke.

### What does the study involve?

Participants will be randomly allocated to one of two groups. While one group will receive traditional rehabilitation, the other group will also receive the new SeStDe program.

### What are the possible benefits and risks of participating?

All participants will receive rehabilitation which may improve their health and physical function. There are no known risks to participants.

### Where is the study run from?

The study takes place at the clinic of nervous diseases of Irkutsk State Medical University (Russia).

When is the study starting and how long is it expected to run for?  
Patients will be enrolled in the study between August 2010 and August 2012. Follow-up examinations will continue until August 2013.

Who is funding the study?  
Irkutsk State Medical University (Russia).

Who is the main contact?  
Dr Yury Bykov  
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## Contact information

**Type(s)**  
Scientific

**Contact name**  
Prof Yury Bykov

**Contact details**  
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664003

## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**  
N/A

## Study information

**Scientific Title**  
A randomised controlled study in patients with ischemic stroke treated with antidepressant sertraline (Stimuloton) and rhythmic stimulation in Irkutsk, Russia

**Acronym**  
SeStDe

**Study objectives**  
Effectiveness rehabilitation in patients with cerebral ischemic stroke remains one of the most actual problems in neurology. A depression following an ischemic stroke is one of the major problems complicating the rehabilitation. We suggest effectiveness of treatment including

traditional therapy, the antidepressant sertraline (Stimuloton), and external rhythmic stimulation in the rehabilitation of patients with post-stroke depression.

### **Ethics approval required**

Old ethics approval format

### **Ethics approval(s)**

Irkutsk State Medical University, 12/12/2006

### **Study design**

Randomised controlled trial

### **Primary study design**

Interventional

### **Secondary study design**

Randomised controlled trial

### **Study setting(s)**

Hospital

### **Study type(s)**

Treatment

### **Participant information sheet**

### **Health condition(s) or problem(s) studied**

Rehabilitation after stroke

### **Interventions**

1. 30 depressive patients were treated by standard treatment
  2. 31 patients received this standard treatment with additional rhythmic stimulation - rhythmic stimulation was presented by light and sound stimulation in individual regimes with hand tapping on keyboard of PC. There are seven regimes of stimulation:
    1. Individual spontaneous rhythm, prescribing frequency of stimulus in following regimes
    2. Sound stimulation with contemporary hands tapping
    3. Sound stimulation with delayed tapping after sound stimulus
    4. Light stimulation with contemporary tapping
    5. Light stimulation with delayed tapping after light stimulus
    6. Light-sound stimulation with contemporary tapping
    7. Light-sound stimulation with delayed tapping after light-sound stimulus
- Every day stimulation will be prescribed for stroke patients. Duration of intervention: 20-21 days. All patients were assessed twice: 1 day (before treatment), 20-21 day (after beginning of prescribed treatment). Catamnesis of patients including this investigation were carried out in 6-12 months.
3. 15 of them received rhythmic stimulation and sertraline (Stimuloton), 100 mg/day
  4. 60 patients had no depressive symptoms

### **Intervention Type**

Drug

**Phase**

Not Applicable

**Drug/device/biological/vaccine name(s)**

Sertraline (Stimuloton)

**Primary outcome measure**

1. Lindmark Scale (LI)
2. The Hamilton Depression Rating Scale (HDRS)
3. The Hospital Anxiety Depression Scale
4. SF-36

Assessed on day of admittance of patients and on day 20 or 21 of treatment

**Secondary outcome measures**

No secondary outcome measures

**Overall study start date**

01/09/2006

**Completion date**

01/03/2012

## Eligibility

**Key inclusion criteria**

1. Patients after ischemic stroke
2. No seizures

**Participant type(s)**

Patient

**Age group**

Adult

**Sex**

Both

**Target number of participants**

121

**Key exclusion criteria**

1. Patients with sever cognitive impairments
2. Epileptic seizures

**Date of first enrolment**

01/09/2006

**Date of final enrolment**

01/03/2012

# Locations

## Countries of recruitment

Russian Federation

## Study participating centre

Krasnogo Vosstania, 1

Irkutsk

Russian Federation

664003

# Sponsor information

## Organisation

Irkutsk State Medical University (Russia)

## Sponsor details

Krasnogo Vosstania, 1

Irkutsk

Russian Federation

664003

## Sponsor type

Hospital/treatment centre

## Website

<http://ismu.baikal.ru>

## ROR

<https://ror.org/05qwrn075>

# Funder(s)

## Funder type

Hospital/treatment centre

## Funder Name

Irkutsk State Medical University (Russia)

# 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