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Sertraline in post Stroke Depression in Irkutsk, Russia

Submission date	Recruitment status	[ ] Prospectively registered
27/02/2012	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
30/03/2012	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
18/09/2014	Circulatory System	[ ] 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
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Contact details
Krasnogo Vosstania, 1
Irkutsk
Russian Federation
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