

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Jun 2026

The effect of organized sensory stimulation program on coma recovery and disease outcomes in comatose stroke patients

Protocol summary

Summary

Objective: To determine the effect of organized sensory stimulation program on coma recovery and disease outcomes in comatose stroke patients STUDY DESIGN: Non-randomized clinical trial, control, phase 2 Study population: Stroke patients with consciousness disorder Inclusion Criteria: age between 35 to 75 years; duration of coma more than 72 hours and less than 14 days; GCS between 6 and 12. Exclusion Criteria: metabolic disorders; get sedative and narcotic medications during the study; sensory -motor disorder; stroke in the areas of visual and auditory nerves Sample size: 80 Intervention: organized sensory stimulation program including auditory, visual, olfactory, gustatory, tactile and kinesthetic for 14 consecutive days. At first select the stimulus according to the patient favours through the families interview and then The list of stimulus that should be used in sensory stimulation program, will be developed. Then the patient will be exposed to stimuli consecutively and regularly. Intervention time: once a day for 14 days. Get every stimulation between 5 to 10 minutes. The consequences of the study: One of the main outcomes is coma recovery. Another one is disease outcomes which include sensory function, cognitive function and The severity of stroke.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016120831299N1**

Registration date: **2017-02-04, 1395/11/16**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-02-04, 1395/11/16

Registrant information

Name

Khadijeh Sargolzaei

Name of organization / entity

Mashhad University of Medical Sciences, School of Nursing and Midwifery

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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research and Technology, Mashhad University of Medical Sciences

Expected recruitment start date

2017-01-08, 1395/10/19

Expected recruitment end date

2017-04-20, 1396/01/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of organized sensory stimulation program on coma recovery and disease outcomes in comatose stroke patients

Public title

Sensory stimulation in Stroke comatose patients

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion Criteria: age between 35 to 75 years; duration of coma more than 72 hours and less than 14 days; GCS

between 6 and 12; the availability of one of the patient's family who is over 18 years; family consent of the patient to participate in the study; Iranian citizenship and fluent in Persian; lack of vision problems and blindness; no hearing problems; the absence of psychotic mental illness; the lack of skin problems; the lack of sedative and narcotic Exclusion Criteria: metabolic disorders; drug addiction; get sedatives and drugs during the study; the prohibition in mobility organs; sensory-motor disorder in four limbs; patients who have suffered from a stroke in the areas of visual and auditory nerves; identification of vision problems; hearing problems; skin diseases and psychological problems during the study; sudden hemodynamic disorder that can cause critical situations for patients; died before the fourteenth days

Age

From **35 years** old to **75 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Not randomized

Randomization description**Blinding (investigator's opinion)**

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids****1****Registry name**

-

Secondary trial Id

-

Registration date

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Mashhad University of Medical Sciences

Street address

Vice Chancellor for Research and Technology,
Mashhad University of Medical Sciences, Next to the
Hoveyzeh Cinema, Daneshgah Avenue

City

Mashhad

Postal code**Approval date**

2016-05-28, 1395/03/08

Ethics committee reference number

941683

Health conditions studied**1****Description of health condition studied**

Stroke

ICD-10 code

G45, G46

ICD-10 code description

Transient cerebral ischaemic attacks and related syndromes, Vascular syndromes of brain in cerebrovascular diseases

Primary outcomes**1****Description**

coma recovery

Timepoint

before and after of intervention for 14 consecutive days

Method of measurement

CRS-R

2**Description**

sensory function

Timepoint

before and after of intervention for 14 consecutive days

Method of measurement

SMART

3**Description**

cognitive function

Timepoint

before and after of intervention for 14 consecutive days

Method of measurement

RLA

4**Description**

the severity of stroke

Timepoint

before intervention at first day, seventh and fourteenth days after intervention

Method of measurement

NIHSS

Secondary outcomes

1

Description

HemodynamicCriteria:PR,RR,BP,SPo2

Timepoint

before and after intervention for 14 consecutive days

Method of measurement

Cardiopulmonary monitoring and Sphygmomanometer

Intervention groups

1

Description

intervention group: Implication of sensory stimulation program include of auditory, visual, olfactory, gustatory, tactile and kinesthetic stimulation. At first select the stimulus according to the patients favourite through families interview and then develop the list of stimulus that should be used in sensory stimulation program. Auditory stimulation will be performed with verbal communication, tape recording of family member voices and patient favorite music. Visual stimulation will be performed with penlight, photographs of family members and mirror. In the beginning of the visual stimulation, the researcher had to hold the patients' eyes open to vision. Olfactory stimulation will be performed with patients' favorite aromas such as perfume, orange or lemon, coffee, vanilla,.. Gustatory stimulation will be performed with irrigation of the oral cavity with cool water, gum massage, brushing of the teeth and then lemon juice will be applied to the lateral side of tongue. Tactile stimulation will be performed with warm and cold water, applying wet towels and then the patient's arms, hands, trunk, and legs will be massaged with olive oil. Finally kinesthetic stimulation will be performed.

Category

Other

2

Description

In the control group will not be performed any intervention except routine care

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Ghaem Hospital

Full name of responsible person

Dr. Mohammad Taghi Farzadfard

Street address

St. Ahmadabad, Dr Shariati Square

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for Research and Technology,
Mashhad University of Medical Sciences

Full name of responsible person

Dr Mohsen Tafaghodi

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Mashhad

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Vice Chancellor for Research and Technology, Mashhad
University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Mashhad University of Medical Sciences, School of
Nursing and Midwifery

Full name of responsible person

Khadijeh Sargolzaei

Position

Master Student

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty