

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 Jun 2026

Effect of shoulder support on improvement of shoulder subluxation in people with stroke

Protocol summary

Study aim

Evaluation of the effect of using shoulder support in reducing shoulder subluxation in people with stroke

Design

A clinical trial with a control and intervention group; single-blind; 50 patients; simple randomization method used for randomization.

Settings and conduct

The study is performed on patients who are referred to Rofideh Rehabilitation hospital from October 1400. Subjects are randomly assigned (using the day of referral: odd days for the intervention group and even days for the control group) in two groups of 25 as a control group: routine intervention and intervention group: common occupational therapy intervention and shoulder support. The person making the necessary assessments is blind to assigning people to the groups.

Participants/Inclusion and exclusion criteria

Be a volunteer to enter the study; Occurrence of stroke; Less than two years have passed since the stroke; Occurrence of partial subluxation in the shoulder joint; No history of the orthopedic shoulder joint disease.

Intervention groups

Intervention group: Performing rehabilitation exercises, in addition to the use of support shoulder throughout the day. Control group: Rehabilitation exercises.

Main outcome variables

Shoulder subluxation; Pain; upper limb function.

General information

Reason for update

Acronym

ESHS

IRCT registration information

IRCT registration number: **IRCT20210620051636N1**

Registration date: **2021-09-18, 1400/06/27**

Registration timing: **prospective**

Last update: **2021-09-18, 1400/06/27**

Update count: **0**

Registration date

2021-09-18, 1400/06/27

Registrant information

Name

Zahra Miri

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 4429 0445

Email address

zahra.ot22@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-09-23, 1400/07/01

Expected recruitment end date

2022-09-23, 1401/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of shoulder support on improvement of shoulder subluxation in people with stroke

Public title

Effect of shoulder support on improvement of shoulder subluxation in people with stroke

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Be volunteer to enter the study
History of stroke
Passing less than two years of stroke
Age between 18 to 60
Having subluxation

Exclusion criteria:

History of having orthopedic disease

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Outcome assessor

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple Randomization. By day of reference, odd day intervention group, even day control group

Blinding (investigator's opinion)

Single blinded

Blinding description

The evaluator who conducts the assessments does not know the participants' groups.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of University of Social Welfare and Rehabilitation

Street address

Koodakyar street, Daneshjoo Blvd , Evin

City

Tehran

Province

Tehran

Postal code

1985713871

Approval date

2021-08-30, 1400/06/08

Ethics committee reference number

IR.USWR.REC.1400.132

Health conditions studied

1

Description of health condition studied

Shoulder subluxation

ICD-10 code

S43.0

ICD-10 code description

Subluxation and dislocation of shoulder joint

Primary outcomes

1

Description

Shoulder subluxation

Timepoint

Before the intervention, three and seven weeks after

Method of measurement

By ultrasound machine and by a specialist doctor

Secondary outcomes

1

Description

pain

Timepoint

Before the intervention, three weeks and seven weeks later

Method of measurement

visual analogue scale

2

Description

Upper limb function

Timepoint

before the intervention Three and seven weeks later

Method of measurement

fugel mayer assessment

Intervention groups

1

Description

Intervention group: Routine occupational therapy interventions will selected during a control panel and performed in 15, 45 minutes, sessions. In addition, they will use the support shoulder at all hours of the day.

Category

Rehabilitation

2

Description

Control group: Routine occupational therapy interventions will selected during a control panel and performed in 15, 45 minutes, sessions.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Rofeideh Rehabilitation hospital

Full name of responsible person

Zahra Miri

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

University of social welfare and rehabilitation sciences

Full name of responsible person

Dr Ebrahim Pishyareh

Street address

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

University of social welfare and rehabilitation sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

University of social welfare and rehabilitation sciences

Full name of responsible person

zahra miri

Position

Occupational therapy

Latest degree

Bachelor

Other areas of specialty/work

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document results

When the data will become available and for how long

a few months after

To whom data/document is available

every one

Under which criteria data/document could be used

informing people

From where data/document is obtainable

zahra miri rofideh hospital

What processes are involved for a request to access data/document

After the approval of the tutor

Comments