Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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
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Iran (Islamic Republic of)
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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
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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
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Occupational therapy
Latest degree
Bachelor
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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