Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Effect of calf muscles dry needling on spasticity,knee and ankle range of motion and function in individuals with chronic stroke: A Randomized Controlled Trial

Protocol summary

Study aim
Determine the effects of dry needling (DN) on spasticity ,knee and ankle range of motion and function in individuals with chronic stroke

Design
A randomized, single-blind clinical trial with a parallel group design. The subjects are randomized with permuted block into two groups (interventional and control)

Settings and conduct
Subjects are recruited from individuals with chronic stroke who refer to Shiraz School of Rehabilitation Sciences.The study is single-blinded and the assessor of MMAS, knee and ankle ROM and TUG test outcome is unaware of subjects allocation to the groups

Participants/Inclusion and exclusion criteria
Inclusion criteria: 6 months after a stroke involving cerebral cortical regions. first-ever unilateral stroke.ankle dorsi flexor MMAS spasticity score ≥ 2. able to ambulate without supportive device exclusion criteria:recurrent stroke. previous treatment with BTXA in the 6 months preceding the study.progressive or severe neurologic diseases, for example, heart conditions, unstable hypertension, fracture, or implants in the lower extremity.fear of needles.any contraindication for deep dry needling

Intervention groups
interventional group: rehabilitation exercises (strengthening exercise, PNF pattern and gait training), stretch of gastrocnemius, soleus and hip adductors muscles and DN over the gastrocnemius, soleus, tibialis anterior and hip adductors muscles on the spastic leg control group: rehabilitation exercises (strengthening exercise, PNF pattern and gait training) and stretch of gastrocnemius, soleus and hip adductors muscles

Main outcome variables
Modified Modified Ashworth Scale (MMAS); range of motion (ROM); Timed up and go (TUG) test

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20091130002793N5**
Registration date: **2019-09-10, 1398/06/19**
Registration timing: **registered_while_recruiting**

Last update: **2019-09-10, 1398/06/19**
Update count: **0**

Registration date
2019-09-10, 1398/06/19

Registrant information

Name
Shahla Zahednejad

Name of organization / entity
School Of Rehabilitation Sciences

Country
Iran (Islamic Republic of)

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+98 61 3374 3102

Email address
snejad@ajums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-04-21, 1398/02/01

Expected recruitment end date
2019-09-18, 1398/06/27

Actual recruitment start date
empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of calf muscles dry needling on spasticity,knee and ankle range of motion and function in individuals with chronic stroke: A Randomized Controlled Trial

Public title

Effect of dry needling on spasticity in individuals with chronic stroke

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

6 months after a stroke involving cerebral cortical regions first-ever unilateral stroke ankle dorsi flexor MMAS spasticity score ≥2 able to ambulate without supportive device

Exclusion criteria:

recurrent stroke previous treatment with BTXA in the 6 months preceding the study progressive or severe neurologic diseases, for example, heart conditions, unstable hypertension, fracture, or implants in the lower extremity fear to needles any contraindication for deep dry needling

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

- Outcome assessor

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

Permuted Block Randomization Randomization was achieved with an online randomization application to provide random permuted blocks with an block size of 4.

Blinding (investigator's opinion)

Single blinded

Blinding description

The assessor of MMAS, knee and ankle ROM and TUG test outcome was unaware of subjects allocation to the groups.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Ahwaz University of Medical Sciences

Street address

Ahwaz Jundishapour University of Medical Sciences, Golestan St,Ahwaz

City

Ahwaz

Province

Khouzestan

Postal code

7194714315

Approval date

2018-12-19, 1397/09/28

Ethics committee reference number

IR.AJUMS.REC.1397.812

Health conditions studied

1

Description of health condition studied

spasticity, knee and ankle range of motion and function in individuals with chronic stroke

ICD-10 code

G81.1

ICD-10 code description

Spastic hemiplegia

Primary outcomes

1

Description

spasticity

Timepoint

before intervention, 3 weeks after first session, immediately after last session and 1 week after last session

Method of measurement

Modified Modified Ashworth Scale

Secondary outcomes

1

Description

knee range of motion

Timepoint

before intervention, 3 weeks after first session, immediately after last session and 1 week after last session

Method of measurement

protractor

2

Description
ankle range of motion
Timepoint
before intervention, 3 weeks after first session, immediately after last session and 1 week after last session
Method of measurement
protractor

3

Description
Functional activity
Timepoint
before intervention, 3 weeks after first session, immediately after last session and 1 week after last session
Method of measurement
Timed Up and Go test

Intervention groups

1

Description
Intervention group:This group will receive rehabilitation exercises (strengthening exercises, PNF pattern and gait training)and stretch of gastrocnemius, soleus and hip adductors muscles for 6 weeks and 2 sessions in each week. Dry needling will apply over gastrocnemius, soleus, tibialis anterior and hip adductors muscles on the spastic leg if necessary.
Category
Treatment - Other

2

Description
Control group: This group will receive rehabilitation exercises (strengthening exercises, PNF pattern and gait training)and stretch of gastrocnemius, soleus and hip adductors muscles for 6 weeks and 2 sessions in each week.
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Shiraz School of Rehabilitation Sciences
Full name of responsible person
Leila Abbasi
Street address
Abiverdi 1 St, Chamran Blvd, Shiraz
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Fars
Postal code
7194733669
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Ahvaz University of Medical Sciences
Full name of responsible person
Mohammad Badavi
Street address
Ahwaz Jundishapur University of Medical Sciences, Golestan St., Ahwaz
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Postal code
1579461357
Phone
+98 61 3336 2414
Email
Badavi-m@ajums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Ahvaz University of Medical 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
Ahvaz University of Medical Sciences
Full name of responsible person
Shahla Zahednejad
Position
Associate professor
Latest degree
Ph.D.
Other areas of specialty/work
Physiotherapy
Street address

Musculoskeletal Rehabilitation Research center,School Of Rehabilitation Sciences, Ahvaz Jundishapur

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Person responsible for scientific inquiries

Contact

Name of organization / entity
Ahvaz University of Medical Sciences

Full name of responsible person
Shahla Zahednejad

Position
Associate professor

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD
The data of the participant alone is useless.

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
Not applicable

Data Dictionary
Not applicable

Title and more details about the data/document
The results of primary outcomes will be shared.

When the data will become available and for how long
two months after the publication of the results.

To whom data/document is available
academic researchers

Under which criteria data/document could be used
Once accessed, individuals have the right to use the study protocol for rehabilitation purposes.

From where data/document is obtainable
Atousa Ebrahimi will be responsive through email. atousa192@yahoo.com

What processes are involved for a request to access data/document
After receiving the request and mentioning the reasons for the request, the data will be answered within a maximum of one month.

Comments