

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 2026

Comparison of the effectiveness of phenol with botulinum toxin injection in lower extremities spasticity

Protocol summary

Study aim

Comparison of the effectiveness of phenol with botulinum toxin injection in lower extremities spasticity

Design

This clinical trial will have two intervention groups, community-based and pragmatic, with parallel groups, one-blind, randomized.

Settings and conduct

This randomized clinical trial will be carried out on referrers to physical and rehabilitation clinics of Shiraz University of Medical Sciences. lower limb spastic patients will be randomly divided into two groups . The randomized blocking method will be used to randomize the patients.

Participants/Inclusion and exclusion criteria

Entry curricula: Completion and signing consent form, People aged 10 to 70 years, passing 5 months of injury, Limited range of motion of the lower limb; Exclusion criteria : coagulation disorders, use of anticoagulant drugs, severe cardiovascular problems, inability to communicate and complete questionnaires, history of allergy and allergic reaction to used drugs

Intervention groups

Group A: 6% phenol injection in aqueous solution for each muscle . Group B treatment: injection of botulinum toxin A in sterile saline solution to a concentration of 100 units per ml and for people with a low weight ,50 units per ml.

Main outcome variables

Improvement of spasticity according to the Ashworth criteria

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170826035914N2**

Registration date: **2019-04-12, 1398/01/23**

Registration timing: **retrospective**

Last update: **2019-04-12, 1398/01/23**

Update count: **0**

Registration date

2019-04-12, 1398/01/23

Registrant information

Name

Azadeh hajihosseini

Name of organization / entity

shiraz university of medical science

Country

Iran (Islamic Republic of)

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+98 71 3231 9040

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-03-21, 1396/01/01

Expected recruitment end date

2019-03-20, 1397/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effectiveness of phenol with botulinum toxin injection in lower extremities spasticity

Public title

Comparison of the effectiveness of phenol with botulinum toxin injection in lower extremities spasticity

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Complete and sign the consent form People aged 10 to 70 years Pass 5 months of damage limited range of motion of lower limb(Ankle,knee,pelvic)

Exclusion criteria:

coagulation disorder use of anticoagulant drugs cardiopulmonary disease Failure to communicate and questionnaire completion history of allergy and allergic reaction to used drugs

Age

From **10 years** old to **70 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **24**

Randomization (investigator's opinion)

Randomized

Randomization description

block randomization

Blinding (investigator's opinion)

Double blinded

Blinding description

Patients are unaware of the type of injectable substance and are randomly divided into two groups A and B. The physician does not know the type of injectable drug of each group and the drug is prepared by someone else.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shiraz University of Medical Sciences

Street address

Faghihi hospital, Karimkhan Ave

City

Shiraz

Province

Fars

Postal code

7134844119

Approval date

2017-05-22, 1396/03/01

Ethics committee reference number

IR.SUMS.MED.REC.1396.24

Health conditions studied

1

Description of health condition studied

Lower limbs spasticity

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Spasticity score accordinge to ashworth scale

Timepoint

Before intervention, 24 hour, 3 weeks after intervention

Method of measurement

Spasticity score accordinge to ashworth scale

Secondary outcomes

1

Description

range of motion of lower limbs

Timepoint

Before intervention, 24 hours and 3 weeks after intervention

Method of measurement

Goniometer

Intervention groups

1

Description

Intervention group: First, the injection of phenol 6% in water solution for each muscle is based on the severity of the spasticity, muscle size and body weight of the patient. The muscles are selected on the basis of stretch and touch or electromyography, and the toxin is injected by the thin needle (Gage 27) at the maximal muscle bulk.

Category

Rehabilitation

2

Description

The second intervention group: botulinum toxin A injection in sterile saline solution up to a concentration of 100 units per ml and for individuals with a low weight, 50

units per milliliter. A botulinum toxin dose selection is based on muscle size, degree of spasticity, and body weight. The muscles are selected on the basis of stretch and touch or electromyography, and the toxin is injected by the thin needle (Gage 27) at the maximal muscle bulk.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Chamran hospital

Full name of responsible person

Azadeh Hajihosseini

Street address

Chamran BLV, Chamran hospital

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Basir Hashemi

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Karimkhan Blv, Shiraz university of medical sciences

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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

Shiraz 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

Shiraz University of Medical Sciences

Full name of responsible person

Hamidreza Farpoor

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Physical Medicine

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Hamidreza Farpoor

Position

Professor

Latest degree

Specialist

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Azadeh Hajihosseini

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Resident

Latest degree

Medical doctor

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

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

Study Protocol

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

Statistical Analysis Plan

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

Informed Consent Form

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

Clinical Study Report

Undecided - It is not yet known if there will be 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