

Clinical Trial Protocol

Iranian Registry of Clinical Trials

12 Jul 2026

Effects of Combination Therapy of Baclofen & Trihexyphenidyl on Early Onset Spasticity in Post Traumatic Brain Injury Patients

Protocol summary

Study aim

The aim of this study was to investigate the effect of combination therapy of baclofen and Trihexyphenidyl in the early treatment of spasticity following trauma.

Design

Clinical trials with 3 groups, factorial groups, Double blind, randomized, phase 2 on 90 patients. Using random digits, a third party will assign them to one of three groups

Settings and conduct

Location: ICU ward of Bahonar Hospital in Kerman The tablets will be given by oral Gavage . Due to the patient's anesthesia, one side will be blind. The treatment regimen is also given by the nurse and therefore the Spasm assessment. Physician will also be unaware of the treatment protocol. Therefore, another side is considered blind.

Participants/Inclusion and exclusion criteria

inclusion Criteria : Patients with acute onset of spasm following trauma in patients with concussion exclusion Criteria : 1. GCS level 3 of 15. 2. Severe drug side effects following baclofen or Trihexyphenidyl . 3. History of severe hypersensitivity to baclofen or Trihexyphenidyl

Intervention groups

The first group received only baclofen with an initial dose of 5 mg three times a day with an increase of 5 mg every three days to a maximum dose of 25 mg three times a day if no response. The second group received Trihexyphenidyl 1 mg per day by increasing the dose of Trihexyphenidyl up to a maximum of 8 mg per day if there is no response and the initial dose of baclofen remains constant in addition to baclofen. The third group received baclofen and Trihexyphenidyl with the condition that the initial dose of Trihexyphenidyl remained constant and the increase in baclofen dose if no response was similar to the first group.

Main outcome variables

Spasm in the muscles of the wrist flexor muscles on one side

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200415047096N1**

Registration date: **2020-09-09, 1399/06/19**

Registration timing: **retrospective**

Last update: **2020-09-09, 1399/06/19**

Update count: **0**

Registration date

2020-09-09, 1399/06/19

Registrant information

Name

pedram arfa

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 34 3223 5011

Email address

parfaf@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-03-31, 1399/01/12

Expected recruitment end date

2020-07-19, 1399/04/29

Actual recruitment start date

2020-04-08, 1399/01/20

Actual recruitment end date

2020-08-19, 1399/05/29

Trial completion date

2020-08-22, 1399/06/01

Scientific title

Effects of Combination Therapy of Baclofen & Trihexyphenidyl on Early Onset Spasticity in Post Traumatic Brain Injury Patients

Public title

Effects of Combination Therapy of Baclofen & Trihexyphenidyl on Spasticity in Brain Injury Patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Early Onset Spasticity in Post Traumatic Brain Injury Patients

Exclusion criteria:

The level of consciousness (GCS) is equal to 3 out of 15
Severe drug side effects following baclofen or Trihexyphenidyl
History of severe allergy to baclofen or Trihexyphenidyl

Age

No age limit

Gender

Both

Phase

2

Groups that have been masked

- Participant
- Care provider
- Outcome assessor

Sample size

Target sample size: **90**

Actual sample size reached: **90**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, patients randomly divided in three groups (30 patients in each group) using random allocation sequence with SAS statistical software. According to this method, a simple randomization list product and patients' involvement in each group determine base on order entry. we used sequentially numbered sealed opaque for allocation concealment.

Blinding (investigator's opinion)

Double blinded

Blinding description

This study was double blinded study. The tablets will be given by oral Gavage. Due to the patient's anesthesia, one side will be blind. The treatment regimen is also given by the nurse and therefore the Spasm assessment Physician will also be unaware of the treatment protocol.

Placebo

Not used

Assignment

Factorial

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of kerman University of Medical Sciences

Street address

Kerman, The beginning of Haft Bagh Alavi Road, Kerman University of Medical Sciences Campus

City

Kerman

Province

Kerman

Postal code

7616913555

Approval date

2020-04-24, 1399/02/05

Ethics committee reference number

IR.KMU.AH.REC.1396.1770

Health conditions studied

1

Description of health condition studied

Spasticity in Post Traumatic Brain Injury Patients

ICD-10 code

Dyskinetic

ICD-10 code description

G80.3

Primary outcomes

1

Description

Spasm in the muscles of the wrist flexor muscles on one side

Timepoint

Spasm in the flexor muscles of the wrist on one side (left hand) is recorded on First day, third day, seventh day, first month, third month, and sixth month after administration.

Method of measurement

Modified Ashworth Scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: In addition to baclofen, Trihexyphenidyl 1 mg per day with increasing dose of Trihexyphenidyl up to a maximum of 8 mg per day if no response and the initial dose of baclofen remains constant

Category

Treatment - Drugs

2**Description**

Control group: Only baclofen is taken with an initial dose of 5 mg three times a day with an increase of 5 mg every three days to a maximum dose of 25 mg three times a day if no response.

Category

Treatment - Drugs

3**Description**

Intervention group: Baclofen and Trihexyphenidyl provided that the initial dose of Trihexyphenidyl remains constant and the dose of baclofen increases if the first group does not respond similarly.

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Shahid Bahonar Hospital in Kerman

Full name of responsible person

Pedram Arfa

Street address

Gharani

City

Kerman

Province

Kerman

Postal code

7613747181

Phone

+98 34 3223 5011

Email

parfaf@gmail.com

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Kerman University of Medical Sciences

Full name of responsible person

Abbas Pardakhti

Street address

Somayeh crossroad

City

Kerman

Province

Kerman

Postal code

7619813159

Phone

+98 34 3226 3815

Email

kmu_research@yahoo.com

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Kerman 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**

Kerman University of Medical Sciences

Full name of responsible person

Pedram Arfa

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Neurosurgery

Street address

Gharani

City

Kerman

Province

Kerman

Postal code

7613747181

Phone

+98 34 3223 5011

Email

parfaf@gmail.com

Person responsible for scientific inquiries**Contact****Name of organization / entity**

Kerman University of Medical Sciences

Full name of responsible person

Mohsen Shahba

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Neurosurgery
Street address
GHarani
City
kerman
Province
Kerman
Postal code
7613747181
Phone
+98 34 3223 5011
Email
mshahba@kmu.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
Kerman University of Medical Sciences
Full name of responsible person
Pedram Arfa
Position
Resident
Latest degree
Medical doctor
Other areas of specialty/work
Neurosurgery
Street address
Gharani
City
Kerman
Province
Kerman
Postal code
7613747181
Phone
+98 34 3223 5011

Email
parfaf@gmail.com

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

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

At the end of the study, some of the information, including the effect of a combination of baclofen and Trihexyphenidyl (with two different doses) on the early treatment of spasm following trauma in stroke patients, was shared with health workers.

When the data will become available and for how long

2 months after data analysis

To whom data/document is available

Health researchers

Under which criteria data/document could be used

In order to use the results and during the written request

From where data/document is obtainable

Pedram Arfa- Email

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

The purpose of accessing data - requesting e-mail

Comments