

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 May 2026

Studying safety and efficacy of Bumetanide on relief of pharmacological treatment-resistant pain in spinal cord injury patients referred to pain clinic of Brain And Spinal Cord Injury Research Center, Emam Khomeini Hospital, Tehran, during years 1392 through 1393

Protocol summary

Summary

The aim of this study is to assess the clinical effect of bumetanide on central neuropathic pain in patients with spinal cord injury. The population under study in this nonrandomized, non-blind, uncontrolled, unicentral, phase 1/2 trial is spinal cord injury-induced pain patients with refractory pain despite at least four weeks of medical treatment. Between 10 to 15 cases would be enough for the study. All the patients which sign the informed consent and do not have exclusion criteria including history of renal failure, creatinin more than 1.5, history of cardiac diseases, evidence of hypokalemia or using medications cross-reacting with bumetanide would be included in the study. Bumetanide tablets would be administered for the patients during four months of study and the effect on pain would be assessed by questionnaire.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201407155368N2**

Registration date: **2014-08-19, 1393/05/28**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2014-08-19, 1393/05/28

Registrant information

Name

Mahmoudreza Hadjighassem

Name of organization / entity

Brain and Spinal Cord Injury research center, SAchool of advanced medical technologies, Tehran Unive

Country

Iran (Islamic Republic of)

Phone

+98 21665815601

Email address

drhadjighassem@iums.ac.ir

Recruitment status

Recruitment complete

Funding source

Brain and Spinal Cord Injury Research Center, Emam Khomeini Hosp.,Tehran

Expected recruitment start date

2014-08-23, 1393/06/01

Expected recruitment end date

2015-04-30, 1394/02/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Studying safety and efficacy of Bumetanide on relief of pharmacological treatment-resistant pain in spinal cord injury patients referred to pain clinic of Brain And Spinal Cord Injury Research Center, Emam Khomeini Hospital, Tehran, during years 1392 through 1393

Public title

Bumetanide Effect on SCI pain relief

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion Criteria: All the patients with spinal cord injury

and refractory at- or below-level pain due to the injury who signed the informed consent. Exclusion Criteria: History of renal failure; Creatinine more than 1.5 mg/dl or its increase at least 0.5 mg/dl during study; Cardiovascular diseases including heart failure, conductive disorders and MI; Hypokalemia during study; During Breast feeding; History of hypersensitivity to sulfonamides, sulfunilurea, carbonic anhydrase inhibitors and thiazides; Using cross-reacting medications like Heart Glycosides, Cisplatin, Glucocorticoids, Cyclosporine, ACE Inhibitors, Aminoglycosides, Beta2 Agonists, Allopurinol, Dofetilide, Probenecid, Risperidone, Sodium Phosphates and Topiramate.

Age

No age limit

Gender

Both

Phase

1-2

Groups that have been masked

No information

Sample size

Target sample size: 15

Randomization (investigator's opinion)

N/A

Randomization description**Blinding (investigator's opinion)**

Not blinded

Blinding description**Placebo**

Not used

Assignment

Single

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Tehran University of Medical Sciences

Street address

Enghelab eslami Street

City

Tehran

Postal code**Approval date**

2014-05-31, 1393/03/10

Ethics committee reference number

113353

Health conditions studied**1****Description of health condition studied**

Neuropathic pain in spinal cord injury

ICD-10 code

T09.3

ICD-10 code description

Injury of spinal cord, level unspecified

Primary outcomes**1****Description**

Pain intensity

Timepoint

Time0, Month4, Month8

Method of measurement

Questionnaire

Secondary outcomes

empty

Intervention groups**1****Description**

Administering oral 1 mg bumetanide tablets, BID, for 4 months.

Category

Treatment - Drugs

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

Brain and Spinal Cord Injury Research Center

Full name of responsible person

Dr Hadjighaddem

Street address

Emam Khomeini Hospital, Keshavarz Bulvard

City

Tehran

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

Brain and Spinal Cord Injury Research Center

Full name of responsible person

Dr Hadjighassem

Street address

Emam Khomeini Hospital, Keshavarz bulvard

City

Tehran

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

organization/entity?

Yes

Title of funding source

Brain and Spinal Cord Injury Research Center

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

empty

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

Brain and Spinal Cord Injury Research Center

Full name of responsible person

Dr Hadjighassem

Position

M.D, PhD in Neuroscience, PostDoctoral Fellow in Cellular and Molecular Neuroscience/ Assistant Prof

Other areas of specialty/work**Street address**

Emam Khomeini Hospital, Keshavarz bulvard

City

Tehran

Postal code**Phone**

+98 21 6643 8635

Fax**Email**

mhaji63@yahoo.com

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

Brain and Spinal Cord Injury Research Center

Full name of responsible person

Dr Hadjighassem

Position

M.D, PhD in Neuroscience, PostDoctoral Fellow in Cellular and Molecular Neuroscience/ Assistant Prof

Other areas of specialty/work**Street address**

Emam Khomeini Hospital, Keshavarz Bulvard

City

Tehran

Postal code**Phone**

+98 21 6643 8635

Fax**Email**

mhaji63@yahoo.com

Web page address**Person responsible for updating data****Contact****Name of organization / entity**

School of Advanced Technologies in Medicine, Tehran University of Medical Sciences

Full name of responsible person

Dr Ebrahim Behzad

Position

M.D, PhD student in neuroscience

Other areas of specialty/work**Street address**

No88, Italia St

City

Tehran

Postal code**Phone**

+98 21 8899 1118

Fax**Email**

ibrahimbehzad@yahoo.com

Web page address**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty