

# 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**

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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**

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

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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

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**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*