

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 2026

Determination of injective dexamethasone efficacy associate with anti venom in decrease of limb edema in snake bite patients

Protocol summary

Summary

This study is a double blind, clinical trial that evaluates the effects of injective dexamethasone associated with anti venom in decrease of limb edema in snake bite patients referring to Razi hospital in Ahvaz after 1 year. Entrances criteria are biting during 6 hours before referring and being in upper or lower limbs. Target sample size is 106 cases. The patients randomize, divided in 2 group with 53 cases, interventional and control. The patients in case group, is treated with dexamethasone 0.4 mg/kg/day as TDS addition to national standard treatment. Sterile water is injected addition to national standard treatment in control group. Also injection continues after removing of edema in bite site, completely. Investigator that doesn't know about kind of treatment and with use a scalingcontain normal saline determines water volume displacement in 0, 6, 18 hours, second day and the final day that removed edema and measures the change of edema. There lated information are recorded.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2012122411873N1**

Registration date: **2013-05-06, 1392/02/16**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2013-05-06, 1392/02/16

Registrant information

Name

Amir Mandegar

Name of organization / entity

Ahvaz Jundishapur University of Medicine Sciences

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Iran (Islamic Republic of)

Phone

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Email address

mandegar.a@ajums.ac.ir

Recruitment status

Recruitment complete

Funding source

Ahvaz Jundishapur University of Medicine Sciences

Expected recruitment start date

2013-03-11, 1391/12/21

Expected recruitment end date

2013-06-11, 1392/03/21

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Determination of injective dexamethasone efficacy associate with anti venom in decrease of limb edema in snake bite patients

Public title

Efficacy of dexamethasone in decrease of limb edema in snake bite patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria : 1)6 hours from bite, 2)Bite in distal of limbs Exclusion criteria : 1)Recieved antivenum before admission, 2)Underlying disease such as : hypertension, peptic ulcer, heart failure, active infection (e.g. varicella, tuberculosis), psychosis, diabetes, glucoma, osteoprosis and other conditions of corticosteroid's contraindications, 3)Recieved any glucocorticoid or NSAIDS drugs

4)Pregnancy and lactation

Age
From **15 years** old to **65 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **106**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Ahvaz Jundishapur University of Medical Sciences

Street address
Esfand St, Golestan Blv.

City
Ahvaz

Postal code
61357-15794

Approval date
2013-03-10, 1391/12/20

Ethics committee reference number
ETA-704

Health conditions studied

1

Description of health condition studied
Snake bite

ICD-10 code
T63.0

ICD-10 code description
Snake venom

Primary outcomes

1

Description
Limb edema

Timepoint
At the admission, 6 hours later, 12 hours later, 18 hours later, second day, third day, other days if admission lenght

Method of measurement
volume of limb according to shift of water in a dish scale in ml

Secondary outcomes

1

Description
Decrease of limb edema

Timepoint
Each 6 hours within the first day of admission and then daily until disappearance of edema

Method of measurement
Immersion of limb in to the scaled dish of normal saline and determination of volume based on ml.

Intervention groups

1

Description
Dexamethasone ampul 0.4mg/kg in 3 devided doses every 8 hours daily till recovery of inflammation

Category
Treatment - Drugs

2

Description
Sterile water (with an equal volume of 0.4 mg/kg from dexamethasone)in 3 devided doses every 8 hours during admission.

Category
Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
Razi Hospital

Full name of responsible person
Ahmad Ghorbani,MD

Street address
Felestin Blv.

City
Ahvaz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research,Ahvaz JondyShapor
University of Medical Sciences

Full name of responsible person

Fegghi,MD

Street address

Esfand St, Golestan Blv.

City

Ahvaz

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

Yes

Title of funding source

Vice chancellor for research,Ahvaz JondyShapor
University of Medical Sciences

Proportion provided by this source**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

2

Sponsor

Name of organization / entity

Vice chancellor for research,Ahvaz JondyShapor
University of Medical Sciences

Full name of responsible person

Fegghi,MD

Street address

Golestan Blv.

City

Ahvaz

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Vice chancellor for research,Ahvaz JondyShapor
University of Medical Sciences

Proportion provided by this source**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

Ahvaz Jundyshapor University of Medical Sciences

Full name of responsible person

Ahmad Ghorbani,MD

Position

Toxicologist

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

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Person responsible for scientific inquiries

Contact

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Full name of responsible person

Ali Reza Mozaffari,MD

Position

Internal medicine

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Person responsible for updating data

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Full name of responsible person

Amir Mandegar,MD

Position

Resident of Internal medicine

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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