

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 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

Country

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Phone

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Email address

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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
length

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

Feghhi,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

Feghhi,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

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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