Clinical Trial Protocol
Iranian Registry of Clinical Trials

06 Nov 2026

Determination of injective dexamethasone efficacy associate with anti venum 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 venum 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 scaling ….contain 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

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Name of organization / entity

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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 venum 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 disapearance 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
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

Person responsible for general inquiries

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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