

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Evaluation of addition of Dexamethason to Antibiothic treatment in case of Septic Arthritis

Protocol summary

Study aim

Evaluation of addition of Dexamethason to Antibiothic treatment in case of Septic Arthritis

Design

All patients will be prescribed Oxazepam 10 mg one hour before bedtime for comfortable sleep at night. In the first group, in addition to standard treatment (Vancomycin 1 g every 12 hours with Ceftazidime 1.5 g every 8 hours), the patient was given an 8-mg Dexamethasone ampoule every 8 hours for 4 days. In the second group, in addition to standard treatment, placebo will be prescribed (distilled water). Clinical and paraclinical signs of patients will be measured at the time of admission and at day 2, day 4 of discharge.

Settings and conduct

All people between the ages of 12 and 90 years who have had a history of recent Corticosteroid use, uncontrolled Diabetes and hypertension of other arthritis (rheumatoid arthritis) will go to Bou Ali Hospital in Qazvin. Of the 146 enrolled, 73 received Dexamethasone along with Antibiotics, and 73 received only Antibiotics.

Participants/Inclusion and exclusion criteria

This study will include all people aged 12 to 90 years. Patients with no history of hypertension, uncontrolled Diabetes and recent Corticosteroid use, Immunodeficiency, Rheumatoid Arthritis and other Autoimmune Diseases that cause joint involvement.

Intervention groups

In the intervention group Dexamethasone 8 mg IV every 8 Hours for 4 Days

Main outcome variables

Duration of hospitalization
Duration of Symptoms
Duration of reduction of paraclinical parameters

General information

Reason for update

Acronym

DSA

IRCT registration information

IRCT registration number: **IRCT20190903044679N1**

Registration date: **2019-12-19, 1398/09/28**

Registration timing: **registered_while_recruiting**

Last update: **2019-12-19, 1398/09/28**

Update count: **0**

Registration date

2019-12-19, 1398/09/28

Registrant information

Name

Amin Karampour

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 28 3333 2230

Email address

a.karampour@qums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-10-23, 1398/08/01

Expected recruitment end date

2020-10-22, 1399/08/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of addition of Dexamethason to Antibiothic treatment in case of Septic Arthritis

Public title

The effect of Dexamethasone in the treatment of Septic Arthritis

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Age>12 and Age<90
Exclusion criteria:
HTN Poor control Diabet Melitius Recent history of Corticosteroid use Immunodeficiency RA Other Autoimmune Diseases that cause joint involvement

Age
From **12 years** old to **90 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Outcome assessor

Sample size
Target sample size: **146**

Randomization (investigator's opinion)
Randomized

Randomization description
The randomization method was randomly removed from the container containing a total of 146 entries including 73 A and 73 B and, as a result, placed the patient in group A or B.

Blinding (investigator's opinion)
Double blinded

Blinding description
In this study, both the researcher and the patient are not aware of Dexamethasone Injections

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Qazvin University of Medical Sciences

Street address

Qazvin , Shahid Bamonar Boulevard,

City

Qazvin

Province

Qazvin

Postal code

59811-34197

Approval date

2019-08-11, 1398/05/20

Ethics committee reference number

IR.QUMS.REC.1398.103

Health conditions studied

1

Description of health condition studied

Pyogenic arthritis

ICD-10 code

M00

ICD-10 code description

Pyogenic arthritis

Primary outcomes

1

Description

Duration of treatment

Timepoint

Daily

Method of measurement

Depending on the length of hospital stay

2

Description

The time it takes for CRP to normalize

Timepoint

Every three days

Method of measurement

Quantity

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Intervention group: 8mg Dexamethasone ampoule will be given every 4 hours for 4 days.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Buali hospital

Full name of responsible person

Amin Karampour

Street address

Buali st

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3413786165
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boali.hospital@qums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Qazvin University of Medical Sciences
Full name of responsible person
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3419915315
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info@qums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Qazvin University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact

Name of organization / entity
Qazvin University of Medical Sciences
Full name of responsible person
Amin Karampour
Position

Resident
Latest degree
Medical doctor
Other areas of specialty/work
Infectious diseases
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Person responsible for scientific inquiries

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Person responsible for updating data

Contact

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be a plan to

make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available