

Clinical Trial Protocol

Iranian Registry of Clinical Trials

20 Jun 2026

The effect of Infliximab injection into calcinosis lesions on patients with juvenile dermatomyositis (JDM)

Protocol summary

Study aim

This study aimed to evaluate the effect of injection of Infliximab into calcinosis lesions caused by juvenile dermatomyositis.

Design

Non-randomized clinical trial, without control group, phase 2, 5 patients, single center

Settings and conduct

The children with juvenile dermatomyositis referred to the rheumatology clinic of Mofid children's hospital, were enrolled in this study. In the beginning, for every 1.5 cm of calcinosis lesion in the patient, 20 mg of Infliximab will be injected at four points around the lesion.

Participants/Inclusion and exclusion criteria

Patients with calcinosis lesions due to juvenile dermatomyositis (up to 18 years) will be included in the study. Patients with a calcinosis lesion larger than 5 cm² will be excluded from the study.

Intervention groups

In the beginning, for every 1.5 cm of calcinosis lesion in the patient, 20 mg of Infliximab will be injected at four points around the lesion. If the lesion is 1.5 to 5 cm², the drug will increase to 40 mg. Injections will be continued weekly for up to ten weeks. Radiographs of patients will be taken before the intervention and after the tenth injection in the tenth week. All patients will have an ultrasound in the fifth week. In addition, the size and number of calcinosis lesions, along with possible side effects reported by patients' parents, are collected weekly and recorded in patient-specific information forms.

Main outcome variables

Number of calcinosis lesions; size of calcinosis lesions; consistency of calcinosis lesions; probable complications of the intervention

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210808052107N1**

Registration date: **2022-07-22, 1401/04/31**

Registration timing: **registered_while_recruiting**

Last update: **2022-07-22, 1401/04/31**

Update count: **0**

Registration date

2022-07-22, 1401/04/31

Registrant information

Name

Foroughossadat Hosseini Moghaddam emami

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2222 7021

Email address

forough.e66@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-04-30, 1401/02/10

Expected recruitment end date

2022-09-10, 1401/06/19

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of Infliximab injection into calcinosis lesions on patients with juvenile dermatomyositis (JDM)

Public title

Evaluation of the effect of Infliximab (a biological drug) on lesions caused by calcium deposition in patients with juvenile dermatomyositis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Definitive diagnosis of juvenile dermatomyositis
Presence of calcinosis lesions

Exclusion criteria:

Patients with Calcinosis lesion size greater than 5 cm²
Presence of calcinosis lesion in life threatening organs

Age

To 18 years old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: 5

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Single

Other design features

In this study, Infliximab is used as an injection into a calcinosis lesion for the first time.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shahid Beheshti University of Medical Sciences

Street address

Arabi Street, Yaman Ave, Shahid Beheshti University of Medical Sciences, Tehran, Iran.

City

Tehran

Province

Tehran

Postal code

1546815514

Approval date

2022-04-26, 1401/02/06

Ethics committee reference number

IR.SBMU.MSP.REC.1401.117

Health conditions studied

1

Description of health condition studied

Juvenile Dermatomyositis (JDM)

ICD-10 code

M33.0

ICD-10 code description

Juvenile dermatomyositis

Primary outcomes

1

Description

Number of calcinosis lesions

Timepoint

At baseline and weekly for up to 10 weeks.

Method of measurement

It will be determined weekly by a pediatric rheumatologist. The number of lesions will be recorded.

2

Description

Size of calcinosis lesions

Timepoint

At baseline and weekly for up to 10 weeks.

Method of measurement

It will be determined weekly by a pediatric rheumatologist. The size of the lesions will be recorded in square centimeters.

3

Description

Consistency of calcinosis lesions

Timepoint

At baseline and weekly for up to 10 weeks.

Method of measurement

It will be determined weekly by a pediatric rheumatologist. The consistency of the lesions will be recorded as the physician estimates whether the lesion is softer or not.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Includes children with juvenile dermatomyositis who have at least two calcinosis lesions. For every 1.5 cm² of calcinosis lesion in the patient, 20 mg of Infliximab will be injected at four points around the lesion. If the size of the lesion is 1.5-5 cm², the amount of injectable drug will increase to 40 mg.

Category

Recruitment centers

1

Recruitment center

Name of recruitment center

Mofid children's hospital

Full name of responsible person

Reza Shiari

Street address

Shariati Ave, Mofid children's Hospital, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1546815514

Phone

+98 21 2222 7033

Email

forough.e66@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Dr. Afshin Zarghi

Street address

No. 2, Yemen St., Shahid Arabi St., Shahid Chamran highway, Tehran, Iran.

City

Tehran

Province

Tehran

Postal code

1546815514

Phone

+98 21 2243 9780

Email

zarghi@sbmu.ac.ir

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

Yes

Title of funding source

Shahid Beheshti 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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Forough Hosseini Moghadam Emami

Position

Subspecialty Assistant in Pediatric Rheumatology

Latest degree

Specialist

Other areas of specialty/work

Pediatrics

Street address

Shariati Ave, Mofid children's hospital, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1546815514

Phone

+98 21 2290 4603

Email

forough.e66@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Forough Hosseini Moghadam Emami

Position

Subspecialty Assistant in Pediatric Rheumatology

Latest degree

Specialist

Other areas of specialty/work

Pediatrics

Street address

Shariati Ave, Mofid Children's hospital, Tehran, Iran.

City

Tehran

Province

Tehran

Postal code

1546815514

Phone

+98 21 2290 4603

Email

forough.e66@gmail.com

Person responsible for updating data

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Forough Hosseini Moghadam Emami

Position

Subspecialty Assistant in Pediatric Rheumatology

Latest degree

Specialist

Other areas of specialty/work

Pediatrics

Street address

Shariati Ave, Mofid children's hospital, Tehran, Iran.

City

Tehran

Province

Tehran

Postal code

1546815514

Phone

+98 21 2290 4603

Email

forough.e66@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

The specific title of the file will be patients' information. In this file, patients' information including age, gender, time of diagnosis, clinical findings, data about the number, size, and consistency of calcinosis lesions in weekly examinations, and reported complications will be shared.

When the data will become available and for how long

The access period will start one month after publishing the results.

To whom data/document is available

Request for data will be possible for all researchers.

Under which criteria data/document could be used

The only condition for using the data will be scientific fidelity and citation to the published study of the present study.

From where data/document is obtainable

Applicants can send their request one month after the publication of the results. Email:

Forough.e66@gmail.com

What processes are involved for a request to access data/document

The applicant should specify the Identification information, including name, surname, organizational affiliation, and the reason for requesting the data in his/her request. After reviewing the application, the requested data will be sent within a week.

Comments