

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Safety and Efficacy of Rituximab in patients with juvenile dermatomyositis (JDM) who were admitted at Mofid children hospital

Protocol summary

Study aim

Investigation of the safety and efficacy of rituximab drug on patients with dermatomyositis in young people

Design

Clinical trial, without control group, single trial, non-blinded, phase 2 on 7 patients

Settings and conduct

The current research will be carried out on children with dermatomyositis referred to Mofid Children's Hospital. Upon entering the study, after receiving the demographic and basic information of the patients, the disease activity status before the intervention (Time 0) will be evaluated by the JDM-DAS tool. Then, patients will be treated with the appropriate dose of rituximab based on their Body Surface Area (BSA).

Participants/Inclusion and exclusion criteria

Conditions for entry: children under the age of 16 with definitive diagnosis of juvenile dermatomyositis based on criteria and have visited Mofid Children's Hospital within the study period. Exclusion criteria: Non-compliance and non-attendance of patients; contraindication for rituximab administration; presence of concomitant diseases and overlap syndrome.

Intervention groups

Children with juvenile dermatomyositis referred to Mofid Children's Hospital, based on the patient's body surface area, are treated with an appropriate dose of rituximab with a time interval (0 and 1 week), with a dose of 575 mg/m² for patients with a body surface area less than or equal to 1.5 and a dose of 750 mg/m² for patients whose body surface area is greater than 1.5. Patients are visited regularly for a period of six months, and a disease activity assessment form (both doctor's and patient's prescriptions) is completed at each visit. In addition, patients and their caregivers are asked about any side effects and effects of treatment.

Main outcome variables

Disease Activity status (physician's score and patient 's score); Improvement of clinical and laboratory symptoms

of the patient; Drug Side Effects

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20231119060108N1**

Registration date: **2024-01-15, 1402/10/25**

Registration timing: **prospective**

Last update: **2024-01-15, 1402/10/25**

Update count: **0**

Registration date

2024-01-15, 1402/10/25

Registrant information

Name

Pooneh Tabibi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2222 7021

Email address

tabibi_p@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-01-21, 1402/11/01

Expected recruitment end date

2024-05-21, 1403/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Safety and Efficacy of Rituximab in patients with juvenile dermatomyositis (JDM) who were admitted at Mofid children hospital

Public title
Safety and Efficacy of Rituximab in patients with juvenile dermatomyositis

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Patient under 16 years old Patients with the diagnosis of dermatomyositis, which is confirmed based on the diagnosis criteria
Exclusion criteria:
Presence of concomitant diseases and overlap syndrome
Contraindications for rituximab injection

Age
To 16 years old

Gender
Both

Phase
2

Groups that have been masked
No information

Sample size
Target sample size: 7

Randomization (investigator's opinion)
N/A

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Shahid Beheshti University of Medical Sciences
Street address
3rd floor, Faculty of Medicine, next to Taleghani Hospital, Evin, Shahid Chamran Highway
City
Tehran
Province
Tehran
Postal code

1983963113

Approval date
2023-12-26, 1402/10/05

Ethics committee reference number
IR.SBMU.MSP.REC.1402.500

Health conditions studied

1

Description of health condition studied
Juvenile dermatomyositis
ICD-10 code
M33.0
ICD-10 code description
Juvenile dermatomyositis

Primary outcomes

1

Description
Disease activity
Timepoint
At the beginning of the intervention (before the start of the intervention), one week, one month, two months, three months, six months and one year after rituximab injection.
Method of measurement
Juvenile Dermatomyositis-Disease Activity Score questionnaire, questionnaire of characteristics and information of dermatomyositis patients

2

Description
Drug Side Effects
Timepoint
One week, one month, two months, three months, six months and one year after rituximab injection.
Method of measurement
Questioning the patient and parents

Secondary outcomes

1

Description
Daily activity and quality of life
Timepoint
Before starting the intervention, one month, two, three months, six months and one year after drug injection
Method of measurement
Juvenile Dermatomyositis-Disease Activity Score questionnaire, questionnaire of characteristics and information of dermatomyositis

Intervention groups

1

Description

Intervention group: Patients based on Body Surface Area (BSA) treated with the appropriate dose of rituximab (575 mg/m² in patients with BSA ≤1.5 m² and 750 mg/m² in patients with BSA>1.5 m²), Two doses one week apart, with the Zitox brand (company Ariogen Pharmed) will be placed

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Mofid childrens hospital

Full name of responsible person

Pooneh Tabibi

Street address

Mofid Children's Hospital, Shariati Street, Tehran

City

Tehran

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1546815514

Phone

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Email

tabibi_p@yahoo.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

Shahid Beheshti University of Medical Sciences,
Research and Technology, student boulevard,
Velanjak, Tehran

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1983963113

Phone

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Email

urm@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

Pooneh Tabibi

Position

Assistant specialist in pediatric rheumatology

Latest degree

Specialist

Other areas of specialty/work

Pediatrics

Street address

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

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Position

Assistant specialist in pediatric rheumatology

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Person responsible for updating data

Contact

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available

Title and more details about the data/document

In the current study, after completing the study, all potential data will be shared with other researchers through the Research Gate data sharing system after de-identifying the patients.

When the data will become available and for how long

Access will start from the time the results are printed.

To whom data/document is available

The data will be publicly available to all interested parties through the link created on the researcher's Research Gate page.

Under which criteria data/document could be used

The use of research data for future studies by referring to the original published article of the current research will be unimpeded.

From where data/document is obtainable

The data will be transparently accessible through the link included in the final article.

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

The data will be transparently accessible through the link included in the final article.

Comments