Clinical Trial Protocol
Iranian Registry of Clinical Trials

29 Jul 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 with 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 children hospital

Full name of responsible person
Pooneh Tabibi

Street address
Mofid Children's Hospital, Shariati Street, Tehran

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Tehran

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1546815514

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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 bouleard, Velanjak, Tehran

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1983963113

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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

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Person responsible for scientific inquiries

Contact

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Shahid Beheshti University of Medical Sciences

Full name of responsible person
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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