Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Evaluating the efficacy and safety of upadacitinib in the treatment of morphea compared to methotrexate in a randomized clinical trial in patients referred to the Morphea Clinic of Razi Hospital

Protocol summary

Study aim

Comparing the efficacy and safety of upadacitinib and methotrexate in adults with plaque or generalized morphea.

Design

This is a single-center, two-arm, parallel-group, randomized clinical trial with a 1:1 allocation ratio. double-blinded, 48 patients. The random allocation sequence was generated using the RAND function in Excel.

Settings and conduct

The study will be conducted at the Morphea Clinic of Razi Hospital, Tehran University of Medical Sciences, Tehran, Iran. Eligible adults with plaque or generalized morphea will be enrolled and randomly assigned to receive upadacitinib or methotrexate. Clinical assessments include the Localized Scleroderma Cutaneous Assessment Tool (LoSCAT), including the Localized Scleroderma Activity Index (LoSAI) and Localized Scleroderma Damage Index (LoSDI), Physician Global Assessment of Activity and Damage. Ultrasonographic assessment of dermal and subcutaneous thickness and elasticity will be performed at baseline and month 6. Laboratory tests will be performed at baseline and during follow-up.

Participants/Inclusion and exclusion criteria

Adults aged 18 years or older with plaque or generalized morphea. Eligible participants must have no systemic treatment for morphea during the previous 6 months and must have a baseline LoSAI of at least 2. Patients with linear morphea, pregnancy or breastfeeding, those who have received systemic treatment for morphea during the previous 6 months, and those who develop adverse events that require discontinuation or are unwilling to continue participation will be excluded.

Intervention groups

Upadacitinib group: oral upadacitinib 15 mg daily. In cases with inadequate response, the dose may be increased to 30 mg once daily. Methotrexate group: methotrexate 15 mg once weekly, with an increase to 25 mg weekly in case of inadequate response

Main outcome variables

Localized Scleroderma Cutaneous Assessment Tool (LoSCAT)

General information

Reason for update

Acronym

BAMDAD

IRCT registration information

IRCT registration number: **IRCT20250228064873N4**
Registration date: **2026-10-02, 1405/07/10**
Registration timing: **prospective**

Last update: **2026-10-02, 1405/07/10**
Update count: **0**

Registration date

2026-10-02, 1405/07/10

Registrant information

Name

Ifa Etesami

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

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Recruitment status

recruiting

Funding source

Expected recruitment start date

2026-11-22, 1405/09/01

Expected recruitment end date

2027-02-20, 1405/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluating the efficacy and safety of upadacitinib in the treatment of morphea compared to methotrexate in a randomized clinical trial in patients referred to the Morphea Clinic of Razi Hospital

Public title

Effectiveness of upadacitinib versus methotrexate in morphea

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

First visit at the Morphea Clinic of Razi Hospital. No systemic treatment for morphea during the preceding 6 months. Baseline LoSAI score ≥2. Diagnosis of plaque or generalized morphea.

Exclusion criteria:

Inability or unwillingness to complete study follow-up. Systemic treatment for morphea during the preceding 6 months. Linear morphea. Pregnancy or breastfeeding. Development of a serious or clinically significant adverse event requiring discontinuation of study treatment.

Age

From **18 years** old to **70 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size

Target sample size: **48**

Randomization (investigator's opinion)

Randomized

Randomization description

Participants will be randomly allocated in a 1:1 ratio to either the upadacitinib group or the methotrexate group using simple randomization. The random allocation sequence will be generated using Random Allocation Software. Each eligible participant will be assigned a unique study identification number, and the generated randomization sequence will determine the treatment group. No stratified or block randomization will be used.

Blinding (investigator's opinion)

Double blinded

Blinding description

Participants and treating physicians will not be blinded because of the differences between the treatment regimens. The clinical outcome assessor, ultrasonography assessor, and data analyst will be blinded to treatment allocation. Clinical and ultrasonographic assessments will be performed by independent assessors who are unaware of the participants' treatment assignments. For data analysis, treatment groups will be identified using coded group labels to maintain blinding of the data analyst.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethics Committee, Faculty of Medicine, Tehran University of Medical Sciences

Street address

Vahdate-Eslami street Razi Dermatology Hospital

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Tehran

Province

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Approval date

2026-09-19, 1405/06/28

Ethics committee reference number

IR.TUMS.MEDICINE.REC.1405.301

Health conditions studied

1

Description of health condition studied

Morphea

ICD-10 code

L94.0

ICD-10 code description

Localized scleroderma [morphea]

Primary outcomes

1

Description

Localized Scleroderma Cutaneous Assessment Tool (LoSCAT)

Timepoint

At baseline before initiation of the intervention, and at month 3 and 6 after initiation of the intervention.

Method of measurement

By a trained outcome assessor who is blinded to treatment allocation.

2

Description
Localized Scleroderma Activity Index (LoSAI)
Timepoint
At baseline before initiation of the intervention, and at month 3 and 6 after initiation of the intervention.
Method of measurement
By a trained outcome assessor who is blinded to treatment allocation.

3

Description
Localized Scleroderma Damage Index (LoSDI)
Timepoint
At baseline before initiation of the intervention, and at month 3 and 6 after initiation of the intervention.
Method of measurement
By a trained outcome assessor who is blinded to treatment allocation.

4

Description
Physician Global Assessment of Activity
Timepoint
At baseline before initiation of the intervention, and at month 3 and 6 after initiation of the intervention.
Method of measurement
By a trained outcome assessor who is blinded to treatment allocation.

5

Description
Physician Global Assessment of Damage
Timepoint
At baseline before initiation of the intervention, and at month 3 and 6 after initiation of the intervention.
Method of measurement
By a trained outcome assessor who is blinded to treatment allocation.

6

Description
Dermal thickness
Timepoint
At baseline and month 6 after initiation of the intervention
Method of measurement
Dermal thickness will be measured using soft-tissue ultrasonography and recorded in millimeters by an ultrasonography assessor blinded to treatment allocation

7

Description
Hypodermal thickness
Timepoint
At baseline and month 6 after initiation of the intervention
Method of measurement
Hypodermal thickness will be measured using soft-tissue ultrasonography and recorded in millimeters by an ultrasonography assessor blinded to treatment allocation

8

Description
Dermal elasticity
Timepoint
At baseline and month 6 after initiation of the intervention
Method of measurement
Dermal elasticity will be measured using soft-tissue ultrasound elastography and recorded in kilopascals by an ultrasonography assessor blinded to treatment allocation.

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Description
Hypodermal elasticity
Timepoint
At baseline and month 6 after initiation of the intervention
Method of measurement
Hypodermal elasticity will be measured using soft-tissue ultrasound elastography and recorded in kilopascals by an ultrasonography assessor blinded to treatment allocation.

10

Description
Occurrence of treatment-related adverse events and serious adverse events
Timepoint
Throughout the treatment period and at each follow-up visit through month 6.
Method of measurement
Adverse events will be recorded and assessed based on participant reports, clinical examination, routine lab tests, and medical record review throughout follow-up.

Secondary outcomes

empty

Intervention groups

1

Description
Upadacitinib group: Participants allocated to the upadacitinib group will receive oral upadacitinib at a dose of 15 mg once daily for 6 months. If predefined inadequate response is observed during follow-up and there is no contraindication to dose escalation, the dose may be increased to 30 mg once daily. The maximum dose will be 30 mg per day. Treatment will be administered throughout the 6-month study period, with clinical assessments at baseline, month 3, and month 6.
Category
Treatment - Drugs

2

Description
Methotrexate group: Participants allocated to the comparator group will receive oral methotrexate at a dose of 15 mg once weekly for 6 months. If predefined inadequate response is observed during follow-up and there is no contraindication to dose escalation, the dose may be increased to 25 mg once weekly. The maximum dose will be 25 mg per week. Treatment will be administered throughout the 6-month study period, with clinical assessments at baseline, month 3, and month 6.

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Razi Hospital

Full name of responsible person
Ifa Etesami

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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Full name of responsible person
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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Tehran 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
Tehran University of Medical Sciences

Full name of responsible person
Ifa Etesami

Position
Associate Professor

Latest degree
Specialist

Other areas of specialty/work
Dermatology

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Specialist

Other areas of specialty/work
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Person responsible for updating data

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Full name of responsible person

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Dermatology

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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

No - There is not a plan to make this available

Clinical Study Report

No - There is not 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

De-identified individual participant data collected during the study, including demographic characteristics, clinical outcome measures, ultrasonographic measurements, treatment allocation, treatment exposure, and safety laboratory data, may be shared upon reasonable request. The shared dataset will not contain directly identifying personal information. Study-related documents, including the study protocol and statistical analysis plan, may also be made available upon reasonable request. Data will not be publicly posted in an identifiable or unrestricted form.

When the data will become available and for how long

Access to de-identified individual participant data and study-related documents will begin 6 months after publication of the primary study results and will remain available for at least 5 years thereafter, subject to ethical and institutional requirements.

To whom data/document is available

Researchers and academic or scientific investigators from universities, research institutions, or other qualified organizations may submit a request for access. Requests from investigators outside academic institutions may also be considered if the proposed use meets the study's ethical and scientific requirements.

Under which criteria data/document could be used

Data may be used for scientifically and ethically appropriate research purposes, including secondary analyses, methodological research, and systematic reviews or meta-analyses. Access will be limited to de-identified data and will not permit attempts to re-identify participants. The proposed use must be consistent with the original informed consent and applicable ethical and institutional requirements.

From where data/document is obtainable

Dr. Ifa Etesami

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

Applicants should submit a written request describing the purpose of the proposed research, the specific data or documents requested, the proposed analyses, and the intended dissemination of the results. Each request will be reviewed by the principal investigator and the research team for scientific merit, ethical compatibility, participant confidentiality, and compliance with institutional requirements. Additional documentation, such as an institutional affiliation or research ethics approval, may be requested when appropriate. Approved data will be provided in a de-identified format after completion of the required review and any applicable data-use agreement. Requests will normally be reviewed within 4 to 8 weeks of receipt of complete documentation.

Comments

Data sharing will be subject to applicable ethical, institutional, and legal requirements. The research team reserves the right to decline requests when data sharing could compromise participant confidentiality, conflict with informed consent, or otherwise violate applicable regulations.