

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

A Randomized Controlled Trial (RCT) to assess the efficacy of multitarget therapy in prevention of avascular necrosis (AVN) in patients taking high dose steroid in two groups (case and control)

Protocol summary

Study aim

A Randomized Controlled Trial (RCT) to assess the efficacy of multitarget therapy in prevention of avascular necrosis (AVN) in patients taking high dose steroid in two groups (case and control)

Design

A randomized clinical trial with parallel groups in the third phase in 70 patients with autoimmune connective tissue diseases and vasculitis requiring high-dose corticosteroid therapy (prednisolone or equivalent with doses higher than 30 mg).

Settings and conduct

A total of 70 patients with autoimmune connective tissue diseases and vasculitis who require high doses of steroids are enrolled in Shariati Hospital. After drug intervention, patients are followed for 1 year. Then, in the third and twelfth months, they undergo a triphasic bone scan to determine if there is evidence of concomitant osteonecrosis

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients with autoimmune connective tissue diseases and vasculitis; Requires treatment with high doses of corticosteroids Exclusion criteria: Co-occurrence of antiphospholipid syndrome; Taking drugs that increase the risk of coagulation, such as oral contraceptives; Occurrence of events leading to increased coagulation such as long-term hospitalization, trauma leading to surgery; Taking anticoagulants; Occurrence of adverse drug reactions in the course of patient assessment.

Intervention groups

The intervention group includes patients in the case group who, in addition to receiving bisphosphate (70 mg weekly), are treated with atorvastatin 40 mg daily, vitamin E (400 mg) daily, and aspirin 80 mg daily.

Main outcome variables

Evidence of osteonecrosis

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210808052105N1**

Registration date: **2022-01-02, 1400/10/12**

Registration timing: **prospective**

Last update: **2022-01-09, 1400/10/19**

Update count: **1**

Registration date

2022-01-02, 1400/10/12

Registrant information

Name

Seyedeh Tahereh Faezi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8822 0065

Email address

tfaezi@sina.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-02-18, 1400/11/29

Expected recruitment end date

2024-02-18, 1402/11/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A Randomized Controlled Trial (RCT) to assess the efficacy of multitarget therapy in prevention of avascular necrosis (AVN) in patients taking high dose steroid in two groups (case and control)

Public title

Assess the efficacy of multitarget therapy in prevention of Avascular necrosis (AVN)

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with autoimmune connective tissue diseases and vasculitis Requires treatment with high doses of corticosteroids

Exclusion criteria:

Co-occurrence of antiphospholipid syndrome Taking drugs that increase the risk of coagulation, such as oral contraceptives Occurrence of events leading to increased coagulation such as long-term hospitalization, trauma leading to surgery Taking anticoagulants Occurrence of adverse drug reactions in the course of patient examination

Age

No age limit

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: 70

Randomization (investigator's opinion)

Randomized

Randomization description

Balance Blocked Randomization method was used for randomization using Stata software. Random allocation is done using size 4 blocks. The total sample size of 70 patients is estimated, including lost to follow up, about 15% of 10 samples were added to the samples to observe the minimum study capacity based on which the sample size was determined in case of sample loss. Thus, using the ralloc module (Random allocation of treatments in controlled trials) in Stata software, random samples were determined for study.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethics Committees of Digestive Disease
Research Institute-Tehran University of Medical Scie

Street address

North Kargar Street, Shariati Hospital, Digestive
Diseases Research Institute

City

Tehran

Province

Tehran

Postal code

1411713135

Approval date

2021-10-17, 1400/07/25

Ethics committee reference number

IR.TUMS.DDRI.REC.1400.036

2

Ethics committee

Name of ethics committee

School of Medicine - Tehran University of Medical
Sciences (Research Ethics Committee)

Street address

Central Building of Tehran University of Medical
Sciences, Qods St., Keshavarz Blvd

City

Tehran

Province

Tehran

Postal code

1416753955

Approval date

2021-02-27, 1399/12/09

Ethics committee reference number

IR.TUMS.MEDICINE.REC.1399.1204

Health conditions studied

1

Description of health condition studied

Osteonecrosis

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Evidence of Osteonecrosis following high-dose
Corticosteroids

Timepoint

In the first three months after starting Corticosteroid and
also one year after starting it

Method of measurement

Three-phasic bone scan

Secondary outcomes

1

Description

Incidence of side effects of drugs

Timepoint

Monthly

Method of measurement

History and Laboratory findings

Intervention groups

1

Description

Intervention group: Includes patients whose multi-target therapies such as atorvastatin 40 mg daily, vitamin E (400 mg) daily, and aspirin 80 mg daily are added to their bisphosphonate (alendronate 70 mg weekly) to prevent osteonecrosis.

Category

Prevention

2

Description

Control group: This includes patients who have added 70 mg alendronate weekly to the patient's treatments.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Dr. Shariati Hospital

Full name of responsible person

Dr. Seyedeh Tahereh Faezi

Street address

Shariati Hospital, Jalal-e-Al-e-Ahmad Hwy

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Email

tfaezi@sina.tums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Mohammad Ali Sahraian

Street address

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vcr@tums.ac.ir

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

Maryam Loghman

Position

Non-faculty specialist physician

Latest degree

Specialist

Other areas of specialty/work

Rheumatology

Street address

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loghmanmaryam@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Seyedeh Tahereh Faezi

Position

Professor

Latest degree

Subspecialist

Other areas of specialty/work

Rheumatology

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Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

Maryam Loghman

Position

Non-faculty specialist physician

Latest degree

Specialist

Other areas of specialty/work

Rheumatology

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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