Clinical Trial Protocol
Iranian Registry of Clinical Trials

27 Jun 2026

Comparison of the effect of intralesional injection of methotrexate and triamcinolone in the treatment of nail psoriasis

Protocol summary

Study aim
Determination of the efficacy of intralesional injection of methotrexate in comparison with triamcinolone in the treatment of nail psoriasis

Design
Phase 3, parallel group, clinical trial, with consecutive sampling, including 50 patients, single blinded, computerized randomized with permuted blocks

Settings and conduct
The study is conducted in the dermatology clinic of Shiraz University of Medical Sciences with intralesional injection of methotrexate in group 1 and intralesional injection of triamcinolone in group 2 every 3 weeks. The patients are assessed at the beginning of treatment, weeks 3,6,9,12,15, and 23 by photography. The investigator is blind to the type of treatment.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Patients between 16 and 70 years of age; Confirmed nail psoriasis of one or more fingernails Exclusion criteria: Involvement of 5 or more nails; Patients who received systemic or topical medication (for nail) in the last 3 months; Patients with skin involvement of more than 20% that need systemic treatment; Patients with nail fungal infection; History of hypersensitivity reactions to lidocaine, triamcinolone, or methotrexate; Diabetic patients; Pregnancy; Lactation; Immunocompromised patients; Active or severe infection; Decreased pulmonary function; Renal failure

Intervention groups
Intervention group: Intralesional injection of methotrexate (Mylan factory, France) in nail matrix and bed, with dose of 5 miligram in each nail, by insulin syringe, every 3 weeks for 4 sessions Control group: Intralesional injection in nail matrix and bed of triamcinolone (Iran-hormone factory, Iran), with dose of 2 miligram in each nail by insulin syringe, every 3 weeks for 4 sessions

Main outcome variables
Severity of nail involvement with psoriasis, measured by modified Nail Psoriasis Severity Index (mNAPSI)

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20140212016557N7**
Registration date: **2021-05-18, 1400/02/28**
Registration timing: **prospective**

Last update: **2021-05-18, 1400/02/28**
Update count: **0**

Registration date
2021-05-18, 1400/02/28

Registrant information

Name
Mozhdeh Sepaskhah

Name of organization / entity
Shiraz University of Medical Sciences

Country
Iran (Islamic Republic of)

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+98 712125239

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sepaskhah@sums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-05-22, 1400/03/01

Expected recruitment end date
2022-04-20, 1401/01/31

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison of the effect of intralesional injection of methotrexate and triamcinolone in the treatment of nail psoriasis

Public title
Effect of injection of methotrexate or triamcinolone in the nail for treatment of nail psoriasis

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Patients between 16 and 70 years of age Clinically- or pathologically confirmed nail psoriasis that have involvement of one or more fingernails with psoriasis

Exclusion criteria:
Patients with involvement of 5 or more nails Patients who received systemic or topical medication (for nail) in the last 3 months Patients with skin involvement of more than 20% that need systemic treatment Patients with nail fungal infection History of hypersensitivity reactions to lidocaine, triamcinolone, or methotrexate Diabetic patients Pregnancy Lactation Immunocompromised patients Patients with active peptic ulcer, gastritis, ascitis, and pleural effusion Concomitant use of hepatotoxic drugs, or drugs that interfere with methotrexate metabolism Concomitant radiotherapy Active or severe infection Decreased pulmonary function Renal failure

Age
From **16 years** old to **70 years** old

Gender
Both

Phase
3

Groups that have been masked

- Outcome assessor

Sample size
Target sample size: **78**

Randomization (investigator's opinion)
Randomized

Randomization description
The participants were randomized using permuted block randomization (size of each block: 4), in individual units, using random allocation software.

Blinding (investigator's opinion)
Single blinded

Blinding description
Due to the difference of the drugs color and texture , the participants and principle investigator cannot be blind. But, data collector and outcome assessors are not aware of the medication of each case.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Shiraz University of Medical Sciences

Street address
Shiraz University of Medical Sciences, Zand St., Shiraz. Iran

City
Shiraz

Province
Fars

Postal code
7134845794

Approval date
2021-04-03, 1400/01/14

Ethics committee reference number
IR.SUMS.MED.REC.1400.008

Health conditions studied

1

Description of health condition studied
Nail psoriasis

ICD-10 code
L40.8

ICD-10 code description
Other psoriasis

Primary outcomes

1

Description
Severity of nail involvement with psoriasis

Timepoint
At the beginning of treatment and weeks 3 ,6, 9, 12, 15, and 23

Method of measurement
modified Nail Psoriasis Severity Index (mNAPSI), measured by inspection and scoring of the severity of psoriasis features in nail matrix and bed

Secondary outcomes

1

Description
Pain severity during injection

Timepoint
At the beginning of treatment and weeks 3 ,6, 9, 12, 15, and 23

Method of measurement
illustrated numerical rating scale

2

Description
Quality of life index
Timepoint
At the beginning and end of treatment
Method of measurement
Dermatology quality of life index questionnaire

Intervention groups

1

Description
Intervention group: Intralesional injection of methotrexate (Mylan factory, France) is done in the nail matrix and bed every 3 weeks for 4 sessions.
Category
Treatment - Drugs

2

Description
Control group: Intralesional injection of triamcinolone (Iran-hormone factory, Iran) is done in the nail matrix and bed every 3 weeks for 4 sessions.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Dermatology clinic, Shahid Faghihi hospital
Full name of responsible person
Mozhdeh Sepaskhah
Street address
Dermatology clinic, Faghihi hospital, Zand St.
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Dr. Abbas Rezaianzade
Street address
Research Council, Shiraz University of Medical Sciences, Zand St., Shiraz, Iran
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Email
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Grant name
Research grant of the Research Council of Shiraz University of Medical Sciences
Grant code / Reference number
18091
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Shiraz 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
Shiraz University of Medical Sciences
Full name of responsible person
Mozhdeh Sepaskhah
Position
دانشیار
Latest degree
Subspecialist
Other areas of specialty/work
Dermatology
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Person responsible for scientific inquiries

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Name of organization / entity
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Full name of responsible person
Mozhdeh Sepaskhah

Position
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Person responsible for updating data

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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
Not applicable

Data Dictionary
Not applicable