Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Comparison of therapeutic effect of low-dose low-molecular-weight heparin (enoxaparin) vs. oral prednisone in treatment of patients with lichen planus

Protocol summary

Summary

The aim of this study is comparing therapeutic effect of low-dose low molecular weight heparin (enoxaparin) versus oral prednisone in patients with disseminated lichen planus. Study population: patients with disseminated lichen planus referred to clinic with no prohibition of drugs or immediate needs for treatment with steroids. Exclusion criteria are severe side effects. The sample size was calculated 23 patients in each group. Patients are randomly divided in two groups. In one group subcutaneous enoxaparin 5 mg is weekly prescribed and in another group patients are treated with 0.5mg/kg prednisone orally daily until complete remission or a maximum of 8 weeks. The results of itching severity according visual analogue scale (VAS), extent of active lesions and drug side effects are compared. In remission, patients are followed for 6 months for recurrent lesions.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2012122211841N1**
Registration date: **2013-01-18, 1391/10/29**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2013-01-18, 1391/10/29

Registrant information

Name

Ahmad Saeidi

Name of organization / entity

Isfahan university of Medical Science

Country

Iran (Islamic Republic of)

Phone

+98 31 1232 2355

Email address

ah_saeidi@resident.mui.ac.ir

Recruitment status

Recruitment complete

Funding source

Isfahan university of medical sciences

Expected recruitment start date

2010-02-21, 1388/12/02

Expected recruitment end date

2012-02-20, 1390/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of therapeutic effect of low-dose low-molecular-weight heparin (enoxaparin) vs. oral prednisone in treatment of patients with lichen planus

Public title

Enoxaparin in treatment of lichen planus

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: patients with disseminated lichen planus at least 6 months represent to the clinic.
Exclusion criteria: 1. Contraindications of heparin and its derivatives, including: hemostasis, acquired or congenital disorder, the risk of bleeding caused by uncontrolled hypertension, active peptic ulcer, recent cerebrovascular accident, sensitivity to enoxaparin or

heparin derivatives; 2. Chronic liver disease; 3. Hepatitis B and C; 4. Contraindications for taking oral prednisone; 5. Medications that are known to lead to the LP like reaction; 6. Lichen planus of nails; 7. Scalp involvement; 8. Ulcerated mucosal lesions; 9. Heparin therapy complications such as drug sensitivity, acute bleeding.

Age
From **18 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **46**

Randomization (investigator's opinion)
Randomized

Randomization description

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
Isfahan University Of Medical Sciences

Street address
Isfahan University Of Medical Science, Hezar jarib st.

City
Isfahan

Postal code

Approval date
2010-02-21, 1388/12/02

Ethics committee reference number
389089

Health conditions studied

1

Description of health condition studied
lichen planus

ICD-10 code
L43.3

ICD-10 code description
lichen planus tropicus

Primary outcomes

1

Description
pruritus

Timepoint
befor treatment-weekly in treatment period- in 1,3 and 6 months following end of treatment

Method of measurement
visual analogue scale(VAS)

2

Description
extention of active lesions

Timepoint
befor treatment-weekly in treatment period- in 1,3 and 6 months following end of treatment

Method of measurement
percentage of skin surface

Secondary outcomes

1

Description
bleeding

Timepoint
weekly in period of treatment

Method of measurement
Observation (yes or no)

2

Description
hypersensitivity

Timepoint
weekly in period of treatment

Method of measurement
Observation (yes or no)

Intervention groups

1

Description
control:The standard treatment of oral prednisolone 0.5 mg per kg daily until complete recovery or up to 8 weeks

Category
Treatment - Drugs

2

Description
intervention: enoxaparin 5 mg subcutaneously weekly until complete remission or a maximum of 8 weeks

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Dermatology clinic of Azahra hospital
Full name of responsible person
Ahmad Saeidi
Street address
Dermatology clinic, Azahra hospital, sofe st.
City
Isfahan

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for Administrative and Financial of Medical School
Full name of responsible person
Dr. Ebrahim Esfandiari
Street address
Vice chancellor for Administrative and Financial of Medical School-Isfahan University Of Medical Science, Hezar jarib st.
City
Isfahan
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice chancellor for Administrative and Financial of Medical School
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

Contact
Name of organization / entity
Isfahan University of Medical Sciences
Full name of responsible person
Ahmad Saeidi
Position
MD, resident of dermatology
Other areas of specialty/work
Street address
Department of Dermatology, School Of Medicine, Isfahan University of Medical Sciences, Hezar jarib st.
City
Isfahan
Postal code
Phone
+98 31 1232 2355
Fax
Email
ah_saeidi@resident.mui.ac.ir
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
Isfahan University of Medical Sciences
Full name of responsible person
Ahmad Saeidi
Position
MD, Resident of dermatology
Other areas of specialty/work
Street address
Isfahan University of Medical Sciences, Hezar jarib st.
City
Isfahan
Postal code
Phone
+98 31 1232 2355
Fax
Email
ah_saeidi@resident.mui.ac.ir ; dr.ahmadsaeidi@yahoo.com
Web page address

Person responsible for updating data

Contact
Name of organization / entity
Isfahan University of Medical Sciences
Full name of responsible person
Ahmad Saeidi
Position
MD, resident of dermatology
Other areas of specialty/work
Street address
School of Medicine, Isfahan University of Medical Sciences, Hezar jarib st.
City
Isfahan
Postal code
Phone
Fax
Email
ah_saeidi@resident.mui.ac.ir
Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty