

Clinical Trial Protocol

Iranian Registry of Clinical Trials

08 Jun 2026

Evaluation of fractional laser and topical antifungal effectiveness versus systemic antifungal in patients with onychomycosis

Protocol summary

Summary

Objectives: This interventional study is a clinical trial to evaluate the fractional laser and topical antifungal effectiveness versus systemic antifungal to improve Onychomycosis. Design: 54 patients in two groups of patients as controls and interventions, each group consisted of 27 patients. Both treatment and advantages and disadvantages of each will be explained. Setting and conduct: Interventions will be treated with fractional laser and topical Terbinafine, 3 sessions with a month intervals between them. The control group will be treated with oral Terbinafine 3 sessions with a month intervals between them. A period of 6 months for follow-up, 3 and 6 months after completion of the treatment will be considered. Inclusion criteria: Onychomycosis Infection; Lack of sensitivity to topical or oral agent Exclusion criteria: Absence of follow up by patients and Lack of consent for treatment; Complications such as allergy to topical or oral agent Intervention: Fractional laser with topical antifungal in the intervention group and the oral antifungal in the control group. Outcome measures variables: Fungal nail infection is the involvement of the nail plate with standard photography.

General information

Acronym

-

IRCT registration information

IRCT registration number: **IRCT2016022925539N6**
Registration date: **2016-04-21, 1395/02/02**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-04-21, 1395/02/02

Registrant information

Name

Abbas Zamanian

Name of organization / entity

Iran University Of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 4401 1989

Email address

a.zamanian@iums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research , Iran University of Medical Sciences

Expected recruitment start date

2015-03-20, 1393/12/29

Expected recruitment end date

2017-03-20, 1395/12/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of fractional laser and topical antifungal effectiveness versus systemic antifungal in patients with onychomycosis

Public title

Evaluation of fractional laser and topical antifungal effectiveness versus systemic antifungal to improve onychomycosis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Onychomycosis Infection ; lack of

topical or oral drug allergy Exclusion criteria: Absence of follow up by patients and Lack of consent for treatment; Complications such as allergy to topical or oral agent

Age

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

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **54**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Randomizing Based on the table of random numbers

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Iran University of Medical Sciences

Street address

Iran University Of Medical Sciences , Adjacent to the Milad Tower , Hemat Highway , Tehran

City

Tehran

Postal code

-

Approval date

2015-09-23, 1394/07/01

Ethics committee reference number

IR.IUMS.REC.1394 . 26856

Health conditions studied

1

Description of health condition studied

onychomycosis

ICD-10 code

B35.1

ICD-10 code description

Tinea unguium

Primary outcomes

1

Description

Fungal nail infection

Timepoint

0, 1 and 2 months during treatment . And 3 and 6 months after treatment

Method of measurement

The involvement of the nail plate with standard photography

Secondary outcomes

1

Description

Response to treatment According to the patient

Timepoint

After completion of treatment

Method of measurement

The percentage and score of the patient to treatment (0 to 100%)

2

Description

Satisfaction amount

Timepoint

After completion of treatment

Method of measurement

Comparison of reduction nail involvement by patient , before and after treatment According to schedule (score 0 to 10)

Intervention groups

1

Description

Intervention group 1 : Cases will be treated with fractional laser, 3 sessions with a month intervals between them and Terbinafine 1 % cream topically twice daily. Due to painful procedure, there is need for anesthesia.

Category

Treatment - Devices

2

Description

Control group : The control group will be treated with oral Terbinafine 250 mg tablet daily for 3 months.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Hazrat Rasool Akram Hospital

Full name of responsible person

Mahba Azizi

Street address

Dermatology clinic, Hazrat Rasool Akram Hospital,
Niayesh Steet, Shahr Aara, Sattarkhan Street, Tehran

City

Tehran

Niayesh Steet , Shahr Aara , Sattarkhan Street ,
Tehran

City

Tehran

Postal code

1445613131

Phone

+98 21 6698

Fax

+98 21 6650 2040

Email

Mahbaazizi@yahoo.com

Web page address

www.IUMS.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research , Iran University of
Medical Sciences

Full name of responsible person

Dr Seyed Ali Javad Mousavi

Street address

Iran University Of Medical Sciences , Adjacent to the
Milad Tower , Hemat Highway , Tehran

City

Tehran

Grant name

-

Grant code / Reference number

-

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

Yes

Title of funding source

Vice chancellor for research , Iran University of Medical
Sciences

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

Iran University Of Medical Sciences

Full name of responsible person

Mahba Azizi

Position

Dermatology Resident

Other areas of specialty/work

Street address

Dermatology department, Hazrat Rasool hospital ,

Person responsible for scientific inquiries

Contact

Name of organization / entity

Iran University Of Medical Sciences

Full name of responsible person

Dr Abbas Zamanian

Position

Associate Professor , Dermatologist

Other areas of specialty/work

Street address

Dermatology department, Hazrat Rasool hospital ,
Niayesh Steet , Shahr Aara , Sattarkhan Street ,
Tehran

City

Tehran

Postal code

1445613131

Phone

+98 21 6698

Fax

+98 21 6650 2040

Email

"Abbaszamanian@yahoo.com" ;

"A.zamanian@iums.ac.ir"

Web page address

www.IUMS.ir

Person responsible for updating data

Contact

Name of organization / entity

Iran University Of Medical Sciences

Full name of responsible person

Mahba Azizi

Position

Dermatology Resident

Other areas of specialty/work

Street address

Dermatology department, Hazrat Rasool hospital ,
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Phone

+98 21 6698

Fax

+98 21 6650 2040

Email**Web page address**

www.IUMS.ir

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