

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Efficacy of topical 0.5% Timolol Maleate in chronic recalcitrant heel fissures

Protocol summary

Study aim

To determine the effectiveness of topical application of 0.5% Timolol Maleate in chronic recalcitrant heel fissures

Design

A Single-arm non randomized clinical trial with a group design of 150 patients enrolled between 06 June 2023 and 12 December 2023, and followed up for 1 month.

Settings and conduct

The study will be conducted on patients reporting in dermatology out-patient-department of a Tertiary care hospital. Data will be collected on a pre-designed proforma. Patients' anonymity will be maintained by keeping their identity hidden, and a code will be generated for them. Confidentiality of the data will be maintained by restricting the data only to the first author or the direct author/s who will collect the data.

Participants/Inclusion and exclusion criteria

Inclusion criteria: patients with chronic heel, plantar fissures. Ages between 18 to 75 years Both genders included Exclusion criteria: Patients taking oral beta blockers Known allergy to beta blockers Patients with chronic dermatosis affecting feet i.e. psoriasis, Reiter's syndrome, keratoderma etc.

Intervention groups

Intervention group includes 150 patients having heel fissures, with no control group for comparison. All will be advised to apply 2-3 drops of Timolol Maleate 0.5% on heel fissures at bet time for 2 weeks, A follow-up will be requested after 2 weeks and 4 weeks of application.

Main outcome variables

Quantitative Variables : age, humidity, room temperature, Measurement of Heel Fissures Qualitative variables, such as Gender, Diabetes, Acute or Chronic Diseases, Pre-existing Skin Condition, Hydra/Aqua Working Environment, Exposure to the chemical on routine basis, Regular use of closed foot ware, Prolong standing workstation and scaling variables such as Severity Scale of Skin, and Photographic Scaling of Heel

General information

Reason for update

Acronym

Heel fissures, cracked heels, sheered heels, Foot eczema

IRCT registration information

IRCT registration number: **IRCT20230712058759N1**

Registration date: **2023-08-30, 1402/06/08**

Registration timing: **retrospective**

Last update: **2023-08-30, 1402/06/08**

Update count: **0**

Registration date

2023-08-30, 1402/06/08

Registrant information

Name

Furqan Warraich

Name of organization / entity

Pakistan Emirates Military Hospital

Country

Pakistan

Phone

+92 51 5403625

Email address

thepresidenthouse@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-06-12, 1402/03/22

Expected recruitment end date

2023-12-12, 1402/09/21

Actual recruitment start date

2023-06-12, 1402/03/22

Actual recruitment end date

2023-07-12, 1402/04/21

Trial completion date

2023-12-12, 1402/09/21

Scientific title

Efficacy of topical 0.5% Timolol Maleate in chronic recalcitrant heel fissures

Public title

To determine effectiveness of topical application of 0.5% Timolol Maleate in treatment of chronic heel recalcitrant fissures

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients having heel, plantar fissures Ages between 18 to 75 years Both male and female

Exclusion criteria:

Patients taking oral beta blockers Known allergy to beta blockers Patients with known dermatoses affecting feet i.e. psoriasis, Reiter's syndrome, keratodermas etc

Age

From **18 years** old to **75 years** old

Gender

Both

Phase

1-2

Groups that have been masked

No information

Sample size

Target sample size: **150**

Actual sample size reached: **120**

Randomization (investigator's opinion)

Not randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Pak Emirates Military Hospital

Street address

259 sec A street 7 askari 14 adiyala road

City

Rawalpindi

Postal code

54000

Approval date

2023-07-05, 1402/04/14

Ethics committee reference number

A/28/EC/556/23

Health conditions studied

1

Description of health condition studied

Heel fissures, sheered heels, cracked heels, foot eczema

ICD-10 code

L85.3

ICD-10 code description

Xerosis cutis

Primary outcomes

1

Description

Measurement of Heel Fissures

Timepoint

2 weeks and 4 weeks.

Method of measurement

With the help of a ruler, heel fissures will be measured and marked with a water-soluble pen. Pictures will be taken to carry out the record of each follow-up and measuring of severity scale.

Secondary outcomes

empty

Intervention groups

1

Description

All the study patients will be advised to apply 2-3 drops of Timolol Maleate 0.5% on chronic, recalcitrant heel fissures over 2 weeks, A follow-up will be requested after 2 weeks and 4 weeks of application. On arrival, patients will be acclimatized for 15 minutes to room temperature and humidity. With the help of a ruler, heel fissures will be marked with a water-soluble pen. Pictures will be taken to carry out the record of each follow-up.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Pak Emirates Military Hospital Rawalpindi

Full name of responsible person

Brig. Nadia Iftikhar

Street address

H2VV+F6R, Abid Majeed Rd, Rawalpindi, Punjab

City

Rawalpindi

Postal code

46000

Phone

+92 51 9273440

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thepresidenthouse@gmail.com

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Pak Emirates Military Hospital

Full name of responsible person

Pakistan Army

Street address

Abid Majeed Road, Rawalpindi

City

Rawalpindi

Postal code

46000

Phone

+92 51 9273440

Email

pemhrawalpindi@gmail.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Pak Emirates Military Hospital

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

Other

Person responsible for general inquiries

Contact

Name of organization / entity

Pak Emirates Military Hospital

Full name of responsible person

Furqan Khan

Position

President ethical committee

Latest degree

Subspecialist

Other areas of specialty/work

Dermatology

Street address

Abid majeed Road Rawalpindi

City

Rawalpindi

Province

Punjab

Postal code

46000

Person responsible for scientific inquiries

Contact

Name of organization / entity

Pak Emirates Military Hospital

Full name of responsible person

Furqan Khan

Position

President ethical committee

Latest degree

Subspecialist

Other areas of specialty/work

Dermatology

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Email

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Person responsible for updating data

Contact

Name of organization / entity

Pak emirates Military Hospital

Full name of responsible person

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Position

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Latest degree

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

There is no further information

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

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