Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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 patents 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. 0n 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

Email
thepresidenthouse@gmail.com

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
Phone
+92 51 9273440
Email
thepresidenthouse@gmail.com

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
Street address
Abid majeed Road Rawalpindi
City
Rawalpindi
Province
Punjab
Postal code
46000
Phone
+92 51 9273440
Email
thepresidenthouse@gmail.com

Person responsible for updating data

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
Phone
+92 51 9273440
Email
thepresidenthouse@gmail.com

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