Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Comparison Of Efficacy Of Single Application Topical 5% Permethrin Versus Single Dose Oral Ivermectin In The Treatment Of Scabies

Protocol summary

Study aim
To compare efficacy of topical 5% permethrin versus oral ivermectin in the treatment of scabies

Design
Total sample size 60 patients divided in two groups of 30 patients each. Both intervention groups . Single center , community based , parallel group , randomized controlled trial.

Settings and conduct
Department of Dermatology Pak Emirates Military Hospital, Rawalpindi.

Participants/Inclusion and exclusion criteria
Inclusion Criteria: ● Patients above 5 years of age and more than 15 kg of weight ● Both genders ● Patients having scabies as per operational definition Exclusion Criteria: ● Pt treated with any scabicidal therapy in the last 01 month ● Pts taking any topical or systemic antibiotic therapy in the week before entry into the study ● H/o allergy to any study drugs ● Immunologically-compromised patients ● H/o secondary bacterial infection ● Pregnancy ● Crusted/Norwegian scabies

Intervention groups
After taking permission from ethical committee of hospital 60 Patients with informed consent, fulfilling the inclusion criteria were included in study. Randomization was conducted through sequentially numbered opaque envelopes generated from a random numbered table into two groups of 30 patients each. Each patient was assigned a number at enrollment which defined a study assignment (topical 5% permethrin versus oral ivermectin).30 patients sample size for 5% permethrin cream group (Group A) while 30 patients sample size for oral ivermectin group (Group B). Permethrin group were asked to apply the cream to whole body covering neck to toe for 12 hrs. Ivermectin grp were given single dose tab ivermectin . Patients were followed up at the end of 1st , 2nd and 4th weeks. Data regarding efficacy from both groups was noted as per operational definition by researcher on especially designed proforma.

Main outcome variables
Pruritus, Scabietic lesions (papules, burrows)

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20221222056891N1**
Registration date: **2023-01-13, 1401/10/23**
Registration timing: **retrospective**

Last update: **2023-01-13, 1401/10/23**
Update count: **0**

Registration date
2023-01-13, 1401/10/23

Registrant information

Name
Tahir Rao

Name of organization / entity
Pak Emirates Military Hospital

Country
Pakistan

Phone
+92 333 7637382

Email address
tahir_rao@yahoo.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-01-01, 1399/10/12

Expected recruitment end date
2021-06-30, 1400/04/09

Actual recruitment start date
2021-01-01, 1399/10/12

Actual recruitment end date

2021-06-30, 1400/04/09

Trial completion date

2021-06-30, 1400/04/09

Scientific title

Comparison Of Efficacy Of Single Application Topical 5% Permethrin Versus Single Dose Oral Ivermectin In The Treatment Of Scabies

Public title

Permethrin and Ivermectin in the Scabies Treatment

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients above 5 years of age and more than 15 kg of weight Both genders Patients having scabies as per operational definition

Exclusion criteria:

Patient treated with any scabicidal therapy in the last 01 month Patients taking any topical or systemic antibiotic therapy in the week before entry into the study H/o allergy to any of the study drugs Immunologically-compromised patients Pregnancy in women Crusted/Norwegian scabies H/o secondary bacterial infection

Age

From **5 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **60**

Actual sample size reached: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization was conducted through sequentially numbered opaque envelopes generated from a random numbers table into two groups of 30 patients each. Each patient was assigned a number at enrollment which defined a study assignment (Topical 5% Permethrin versus Oral Ivermectin).Method of randomization was simple and unit individual.

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

Ethical Committee Pak Emirates Military Hospital

Street address

Peshawar road, rawalpindi saddar

City

Rawalpindi

Postal code

46000

Approval date

2020-12-08, 1399/09/18

Ethics committee reference number

A/28/EC/80/2020

Health conditions studied

1

Description of health condition studied

Scabies

ICD-10 code

B86

ICD-10 code description

Scabies

Primary outcomes

1

Description

Pruritus

Timepoint

At the time of treatment and at 1st, 2nd and 4th week after intervention.

Method of measurement

History for pruritus (relieved/not relieved)

2

Description

Scabietic Lesions (Burrows and Papules)

Timepoint

At the time of treatment and at 1st, 2nd and 4th week after intervention

Method of measurement

Clinical Examination and Dermoscopy for scabietic lesions (present/not present)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Permethrin Group(A): 30 patients

fulfilling inclusion criteria were prescribed permethrin 5% cream. They were asked to apply the cream to whole body covering neck to toe. After application patient were to wear clothes. They were explained that the cream must remain in contact with the skin for at least 12 hours and not to take bath before 12 hours after application. Patients were asked to take bath after 12 hrs . If any other family member was having similar symptoms he was also prescribed same medication. Patients were evaluated at week 1,2 and 4 after the treatment for resolution of pruritus and scabietic lesions and development of any adverse effects.

Category

Treatment - Drugs

2

Description

Intervention group: Intervention group(B): 30 patients fulfilling inclusion criteria received oral ivermectin 200ug/kg(Tab Ivermite) single dose only and were evaluated at week 1,2 and 4 after the treatment for resolution of pruritus and scabietic lesions and development of any adverse effects.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Pak Emirates Military Hospital

Full name of responsible person

Rao Muhammad Tahir Sattar

Street address

Pedhawar road, Rawalpindi saddar

City

Rawalpindi

Postal code

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Phone

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Email

tahir_rao@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Pak Emirates Military Hospital

Full name of responsible person

Rao Muhammad Tahir Sattar

Street address

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Email

tahir_rao@yahoo.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

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Pak Emirates Military Hospital

Full name of responsible person

Tahir Rao

Position

Consultant

Latest degree

Specialist

Other areas of specialty/work

Dermatology

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

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Position

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
Yes - There is a plan to make this available

Statistical Analysis Plan
Yes - There is a plan to make this available

Informed Consent Form
Yes - There is a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
Yes - There is a plan to make this available

Data Dictionary
Yes - There is a plan to make this available

Title and more details about the data/document
Deidentified Individual participant data like age, weight, duration of disease, gender, given drug and response to treatment will be shared. Efficacy with respect to duration of disease, gender, age and weight will also be provided.

When the data will become available and for how long
Data will be shared after the publication of the article likely by end of 2023.

To whom data/document is available
To the people associated with medical profession.

Under which criteria data/document could be used
Documents would be used for educational purposes and will be shared by mail and will be entertained by primary researcher.

From where data/document is obtainable
Data could be obtained from primary researcher as well as from Department of dermatology pak Emirates Military Hospital.

What processes are involved for a request to access data/document
Data could be obtained by mail and in person from hospital after approval from competent authority.

Comments