

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Efficacy and Safety of moxidectin versus ivermectin for treatment of human scabies: A randomized clinical trial

Protocol summary

Study aim

Compare efficacy and safety of moxidectin and ivermectin in treatment of patients with scabies.

Design

This is a single-blind, Two parallel groups, randomized controlled Phase 2 trial

Settings and conduct

This study will be held in Tanta city, Gharbia, Egypt, patients attending at dermatology outpatient clinic in Tanta University hospital. Scabies will be diagnosed by history, examination of skin to detect presence of burrows or excoriated papules or scratching marks in predilection sites, and detection of mites (*Sarcoptes scabii*) by microscopic examination. Then, patients who will accept participation and sign an informed consent will be randomly allocated into two groups. Patients will be blinded by application of medication in containers marked A or B. After using either ivermectin or moxidectin, reevaluation will be made clinically and microscopically to compare the efficacy of both drugs.

Participants/Inclusion and exclusion criteria

The study will be carried out on patients attending the dermatology outpatient clinic Inclusion criteria: Patients diagnosed with scabies: 1.Intense pruritus especially at night. 2.Typical distribution of the excoriated papulovesicular lesions 3.Affection of other family members 4.Detection of *Sarcoptes Scabiei* mites in cutaneous scrapings Exclusion criteria: Patients with recent topical or systemic treatments of scabies; clinical bacterial infection or any other associated skin disease; evident systemic diseases causing pruritus; pregnant; and lactating

Intervention groups

Group A (50 patients): Treated by moxidectin (Cydectin®) once Group B (50 patients): Treated by ivermectin (Iverzine®) once daily for 3 successive days

Main outcome variables

The treatment efficacy will be evaluated by clinical lesions, degree of pruritus and mites count

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20191030045275N1**

Registration date: **2020-02-20, 1398/12/01**

Registration timing: **prospective**

Last update: **2020-02-20, 1398/12/01**

Update count: **0**

Registration date

2020-02-20, 1398/12/01

Registrant information

Name

Ahmad El-Ebiary

Name of organization / entity

Faculty of Medicine, Tanta University

Country

Egypt

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Email address

a.ebiary@med.tanta.edu.eg

Recruitment status

Not yet recruiting

Funding source

Expected recruitment start date

2641-08-23, 2020/06/01

Expected recruitment end date

2642-02-20, 2020/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Efficacy and Safety of moxidectin versus ivermectin for treatment of human scabies: A randomized clinical trial

Public title

Effect of moxidectin in treatment of scabies

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

(A) Clinical: 1. Intense pruritus especially at night. 2. Typical distribution of the excoriated papulovesicular lesions; around umbilicus, flexures, genitalia, interdigital spaces. 3. Affection of other family members. (B) Parasitological: By detection of *Sarcoptes Scabiei* mites (adult, larvae and eggs) in cutaneous scrapings.

Exclusion criteria:

Patients with recent topical or systemic treatments of scabies. Patients with clinical bacterial infection or any other associated skin disease. Patients with any evident systemic diseases causing pruritus. Pregnant and lactating women.

Age

To 60 years old

Gender

Both

Phase

2

Groups that have been masked

- Participant
- Data analyser

Sample size

Target sample size: 100

Randomization (investigator's opinion)

Randomized

Randomization description

We used the sealed, opaque sequentially numbered envelopes method for randomization and allocation concealment of patients included in this trial. We used 100 identical, opaque, letter-sized envelopes. We used 2 rolls of household aluminum cooking foil that we cut into 100 sheets (of the same width as and twice the height of the envelope). We prepared 100 envelope-sized sheets of white paper and 100 envelope-sized sheets of single sided carbon paper. We wrote "Treatment A" on 50 paper sheets and "Treatment B" on the other 50 sheets. To prepare 50 Treatment A envelopes, we selected one envelope-sized sheet of of Treatment A and placed one sheet of carbon paper on top of the Treatment A allocation paper with the carbon side facing the paper, then we put both papers inside a foil wrapper. Then, the completed insert was placed into a blank envelope with the carbon paper closest to the front of the envelope. Finally, the envelop was sealed and we signed across the seal. We completed all the 50 Treatment A envelopes the same way. We prepared 50 Treatment B envelopes the same way as Treatment A envelopes. Both sets of envelopes were combined and we shuffled them thoroughly. Then, using a pen we marked a number on the front of each envelope sequentially from 1 to 100. The carbon paper inside the envelope will transfer this

number to the allocation paper inside. Finally, we placed these envelopes into a plastic container, in numerical order, ready for use. Doig GS, Simpson F. Randomization and allocation concealment: a practical guide for researchers. *J Crit Care* 2005;20:187-93.

Blinding (investigator's opinion)

Single blinded

Blinding description

This trial is a single blind study for the participant involved. We will achieve this by making a letter for each medication used and masking the name of the medication.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethics Committee of Tanta Faculty of Medicine

Street address

El-Giesh Street, Medical Campus of the Faculty of Medicine, Tanta University

City

Tanta

Postal code

31527

Approval date

2640-08-03, 2019/05/12

Ethics committee reference number

33106/ 05/19

Health conditions studied

1

Description of health condition studied

patients diagnosed of having scabies

ICD-10 code

B86

ICD-10 code description

Scabies

Primary outcomes

1

Description

Clinical lesions and degree of pruritus

Timepoint

1 week after intervention

Method of measurement

Clinical evaluation

2

Description

Mites count

Timepoint

1 week after intervention

Method of measurement

Microscopic examination of mites

Secondary outcomes

empty

Intervention groups

1

Description

Group A (50 patients): Treated by application of topical formulation of moxidectin (Cydectin®) once.

Category

Treatment - Drugs

2

Description

Control group: Group B (50 patients): Treated by application of topical ivermectin (Iverzine®) once per day for 3 successive days.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Dermatology outpatient clinic, Tanta Univesity Hospital

Full name of responsible person

Hager Soliman El sayed Zoghroban

Street address

El-Giesh Street, Medical Campus of the Faculty of Medicine, Tanta University

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Faculty of Medicine, Tanta University

Full name of responsible person

Prof. Ahmed Mohammed Al-Metwally Ghoneim

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Faculty of Medicine, Tanta University

Proportion provided by this source

50

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

Tanta University

Full name of responsible person

Dr. Mohamed Fawzy

Position

Lecturer

Latest degree

Ph.D.

Other areas of specialty/work

Dermatology

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Faculty of Medicine, Tanta University

Full name of responsible person

Prof. Ahmad El-Ebiary

Position

Professor

Latest degree

Ph.D.

Other areas of specialty/work

Toxicology

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Person responsible for updating data

Contact

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Tanta university

Full name of responsible person

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Latest degree

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Other areas of specialty/work

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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

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

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available

Title and more details about the data/document

All IPD that underlie results in a publication and study protocol

When the data will become available and for how long

beginning 9 months and ending 36 months following article publication

To whom data/document is available

Researchers whose proposal for the use of data has been approved by an independent review committee identified for this purpose

Under which criteria data/document could be used

for IPD meta-analysis

From where data/document is obtainable

from the PI

What processes are involved for a request to access data/document

A proposal for the use of data to be submitted to the PI, then evaluated by an independent review committee identified for this purpose

Comments