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 Scabeii 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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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 Scabeii 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 envelops, 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 envelops the same way. We prepared 50 Treatment B envelops the same way as Treatment A envelops. Both sets of envelops 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
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Faculty of Medicine, Tanta University
Full name of responsible person
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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

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Name of organization / entity
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Full name of responsible person
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Position
Professor

Latest degree
Ph.D.

Other areas of specialty/work
Toxicology

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Person responsible for updating data

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Tanta university

Full name of responsible person
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Position
Lecturer

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Other areas of specialty/work
Dermatology

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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