Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Comparison of therapeutic effects of topical colloidal silver and topical clotrimasole in dermatophytosis

Protocol summary

Summary

(1) Objectives: Our aim in this study is to compare topical colloidal silver with topical clotrimasole in treating patients with dermatophytosis. (2) Design: This is a double blinded randomized clinical trail. Forty patients with staphylococcal-streptococcal skin infections and 40 ones with dermatophytosis referring to dermathology clinics, Sina Hospital, Tabriz will be included in the study after qualifying the inclusion and exclusion criteria and obtaining the informed consent. Patients will be randomly assigned to one of treatment groups. For randomizing the patients we will use Excel software (computerized randomization). (3) Setting and conduct: After randomizing the patients, one group will receive topical colloidal silver and the other will be administered with clotrimasole. Neither the patient nor the supervisor doctor are aware of the administered drug. Inclusion criteria are having superficial staphylococcal-streptococcal skin infections, being more than 4 years old, not having immune disorder and organ failure, not having history of allergy to silver compounds and clotrimasole and not using topical drugs in last two weeks in the site of lesion. Exclusion criteria are unwillingness to continue participation in the study, occurring a dermatological reaction due to drugs administered and any kind of drug reaction. (4) Interventions: Patients in the first group will receive topical colloidal silver three times a day for two weeks. In the other group patients will receive topical clotrimasole two times a day for four weeks. (5) Main outcome measures: Erythema, encrustation, inflammation and exudation will be evaluated before administering drugs and at the end of treatment period.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201401045092N2**

Registration date: **2014-08-29, 1393/06/07**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2014-08-29, 1393/06/07

Registrant information

Name

Effat Khodayiani

Name of organization / entity

Tabriz University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Tabriz University of Medical Sciences

Expected recruitment start date

2013-03-21, 1392/01/01

Expected recruitment end date

2013-11-22, 1392/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of therapeutic effects of topical colloidal silver and topical clotrimasole in dermatophytosis

Public title
Comparison of two kinds of topical drugs in treatment of dermatological infections
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria: superficial staphylococcal-streptococcal skin infections; age more than 4 years old; not having immune disorder and organ failure; not having history of allergy to silver compounds and clotrimasole; not using topical drugs in last two weeks in the site of lesion.
Exclusion criteria: unwillingness to continue participation in the study, occurring a dermatological reaction due to drugs administered; any kind of drug reaction.
Age
From **4 years** old to **149 years** old
Gender
Both

Phase
3
Groups that have been masked
No information
Sample size
Target sample size: **80**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Double blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Tabriz University of Medical Sciences
Street address
Ethics committee, Tabriz University of Medical Sciences, Golgasht Street, Azadi Street, Tabriz
City
Tabriz
Postal code
Approval date
2013-02-24, 1391/12/06
Ethics committee reference number
5/4/11391

Health conditions studied

1

Description of health condition studied
Dermatophytosis
ICD-10 code
B35.9
ICD-10 code description
Dermatophytosis, unspecified

2

Description of health condition studied
ůperficial staphylococcal-streptococcal skin infections
ICD-10 code
A49.1
ICD-10 code description
Streptococcal infection, unspecified site

Primary outcomes

1

Description
Erythema
Timepoint
Before starting the study and at the end of study
Method of measurement
Clinical evaluation and grading based on complete treatment, partial treatment and no treatment

2

Description
Encrustation
Timepoint
Before starting the study and at the end of study
Method of measurement
Clinical evaluation and grading based on complete treatment, partial treatment and no treatment

3

Description
Inflammation
Timepoint
Before starting the study and at the end of study
Method of measurement
Clinical evaluation and grading based on complete treatment, partial treatment and no treatment

4

Description
exudation
Timepoint
Before starting the study and at the end of study
Method of measurement
Clinical evaluation and grading based on complete treatment, partial treatment and no treatment

Secondary outcomes

empty

Intervention groups

1

Description
In the treatment group, patients will receive topical colloidal silver three times a day for two weeks.
Category
Treatment - Drugs

2

Description
In the control group patients will receive clotrimasole two times a day for four weeks.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Sina Hospital
Full name of responsible person
Dr. Afsaneh Parvaneh
Street address
Department of Dermathology, Sina Hospital, Azadi Street, Tabriz
City
Tabriz

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for research, Tabriz University of Medical Sciences
Full name of responsible person
Dr. Seyyed Kazem Shakouri
Street address
Contact details : Vice chancellor for research, Tabriz University of Medical Sciences, Daneshgah square, Tabriz
City
Tabriz
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice chancellor for research, Tabriz University of Medical Sciences
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

Contact
Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
Dr. Afsaneh Parvaneh
Position
Dermatholgy resident
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Person responsible for scientific inquiries

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Person responsible for updating data

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Name of organization / entity
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Position

Dermathology resident

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty