

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

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

Protocol summary

Summary

(1) Objectives: Our aim in this study is to compare topical colloidal silver with topical clotrimazole in treating patients with dermatophytosis. (2) Design: This is a double blinded randomized clinical trial. Forty patients with staphylococcal-streptococcal skin infections and 40 ones with dermatophytosis referring to dermatology 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 clotrimazole. 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 clotrimazole 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 clotrimazole 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)

Phone

+98 41 1541 2101

Email address

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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 clotrimazole 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 clotrimazole; 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, Goltasht 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

Superficial 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 clotrimazole 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 Dermatology, 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

Dermatology resident

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

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Full name of responsible person

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Position

Associate professor of Dermatology

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Dr. Afsaneh Parvaneh

Position

Dermatology 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