Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Nov 2026

The effect of fluconazole lozenge on oral candidiasis in immunocompromised patients: an experimental study and a randomized clinical trial

Protocol summary

Study aim
Evaluation of the clinical effectiveness of fluconazole lozenges in the treatment of oral candidiasis

Design
In this study, the phase 3 clinical trial is conducted on 50 patients, the patients are randomly divided into two groups of fluconazole and control (25 people in each group). The placement of patients in these two groups is simple and based on the RAND function of Excel software. This study is double-blind, and the doctor and the patient do not know which group they are in

Settings and conduct
A double-blind randomized controlled clinical trial related to oral candidiasis in patients admitted to Shahid Sadoughi Hospital in Yazd is conducted on 50 patients in two control and intervention groups. The physician and the statistical analyst do not know the type of intervention of the studied groups

Participants/Inclusion and exclusion criteria
Inclusion criteria: Age 18 to 70 years Women are not pregnant or lactating No history of fluconazole allergiy Exclusion criteria: occurrence of allergic reaction to fluconazole exacerbation of the disease

Intervention groups
In the current study, patients will be divided into two groups: the group receiving fluconazole lozenges, the group receiving standard treatment.

Main outcome variables
Cotton feeling in the mouth, loss of taste, total area of oral candidiasis lesions

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20191106045356N16**

Registration date: **2023-01-25, 1401/11/05**

Registration timing: **registered_while_recruiting**

Last update: **2023-01-25, 1401/11/05**

Update count: **0**

Registration date

2023-01-25, 1401/11/05

Registrant information

Name
Mohsen Zabihi

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 35 3820 3865

Email address
mzabihi100@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-12-06, 1401/09/15

Expected recruitment end date

2023-03-11, 1401/12/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of fluconazole lozenge on oral candidiasis in immunocompromised patients: an experimental study and a randomized clinical trial

Public title

The effect of fluconazole lozenge on oral candidiasis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

The patient is undergoing cancer chemotherapy in Yazd hospitals. The woman should not be pregnant or lactating. Willingness to participate in the study and complete the informed consent form Age 18 to 70 years

Exclusion criteria:

The occurrence of an allergic reaction to fluconazole Aggravation of the disease and the need for drug intervention to control the disease Non-cooperation in the use of medication

Age

From **18 years** old to **70 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Data analyser

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients who meet the inclusion criteria receive one of the drugs labeled A or B by a simple randomization method based on the random number function (RAND), of Excel software. Intervention with each of these drugs four times a day and It is done for 7 days. On the 1st, 3rd, 7th, and 14th days from the beginning of the intervention, cotton sensation in the mouth, loss of taste, and pain during eating and swallowing are checked.

Blinding (investigator's opinion)

Triple blinded

Blinding description

Both placebo lozenges and placebo drops are prepared and placed next to lozenges containing fluconazole and nystatin drops in coded uniform containers. Patients of both study groups receive both lozenges and drops, one of which contains medicine and the other placebo. The prescribing phusician, the patient, and the data analyzer are not aware of their content.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shahid Sadoughi University of Medical Sciences

Street address

Alem sq.

City

yazd

Province

Yazd

Postal code

8916978477

Approval date

2021-10-27, 1400/08/05

Ethics committee reference number

IR.SSU.MEDICINE.REC.1400.201

Health conditions studied

1

Description of health condition studied

Oral candidiasis

ICD-10 code

B37.0

ICD-10 code description

Candidal stomatitis

Primary outcomes

1

Description

Total area of oral candidiasis lesions

Timepoint

At the beginning of the treatment and after every 2 days until 10 days, the condition of oral candidiasis lesions is evaluated in terms of the total area of the lesions.

Method of measurement

Determining the total area of oral candidiasis lesions through Fiji software

Secondary outcomes

1

Description

Cotton feeling in the mouth

Timepoint

the beginning of the treatment and after every 2 days up to 10 days, the condition of oral candidiasis lesions is evaluated in terms of the feeling of cotton in the mouth (score 0 to 4).

Method of measurement

Scoring the feeling of cotton in the mouth using a questionnaire

2

Description

Decreased taste

Timepoint

At the beginning of treatment and after every 2 days until 10 days, the condition of oral candidiasis lesions is evaluated in terms of taste loss (score 0 to 4).

Method of measurement

Scoring of taste reduction using a questionnaire

Intervention groups

1

Description

Intervention group: Including 25 patients hospitalized in Yazd hospitals and undergoing cancer chemotherapy, who were diagnosed with oral candidiasis and met the inclusion criteria, and were randomly selected based on the RND function of Excel software. Patients in the fluconazole group use lozenges containing 20 mg of fluconazole orally 4 times a day on days 1 to 10. In this research, fluconazole lozenges are prepared using fluconazole powder purchased from Amin Pharmaceutical Company, which has a license from the Food and Drug Organization of Iran. At the beginning of the treatment and after every 2 days until 10 days, the condition of oral candidiasis lesions in terms of the total area of the lesions (score 0 to 4), intervention of cotton sensation in the mouth (score 0 to 4), loss of taste, (score 0 to 4) and the number of lesions are evaluated.

Category

Treatment - Drugs

2

Description

Control group: Including 25 patients hospitalized in Yazd hospitals and undergoing cancer chemotherapy, who were diagnosed with oral candidiasis and met the inclusion criteria, and were randomly selected based on the RND function of Excel software. Nystatin group patients use 20 drops of nystatin orally 4 times a day on days 1 to 10. In this study, Nystatin drops are obtained from Emad Pharmaceutical Company, which has a license from the Food and Drug Organization of Iran. At the beginning of the treatment and after every 2 days until 10 days, the condition of oral candidiasis lesions in terms of the total area of the lesions (score 0 to 4), intervention of cotton sensation in the mouth (score 0 to 4), loss of taste, (score 0 to 4) and the number of lesions are evaluated.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

hospitals

Full name of responsible person

Dr. Mohsen Zabihi

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Yazd University of Medical Sciences

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

Yazd University of Medical Sciences

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

Yazd University of Medical Sciences

Full name of responsible person

Dr. Mohsen Zabihi

Position

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available