Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparison of Pomegranate peel extract anticandidal activity and nystatin in patients with oral candidiasis

Protocol summary

Summary

The purpose of this study is to compare the antifungal effect of Punica granatum L. (Pomegranate) peel extract and nystatin against oral candidiasis (oral thrush). In this randomized, double-blind clinical trial, 60 patients with oral candidiasis will be selected of patients who referred to Dermatology Center of Razi Hospital. Identification of oral candidiasis will be confirmed by microscopic morphology and culture. The patients will randomly allocate in two groups of 30 individuals each according to the medication prescribed: Group-I (control group) will use oral nystatin. Group-II (experimental group) will use the P. granatum peel extract as oral gel. Neither the patients nor the physician knows which participants belong to the control group. The oral gel contains pomegranate peel extract will be prepared in Jaber Ebne Hayyan Pharmaceutical Company. All groups use the medicines three times per day for 14 days. After first week and second week the patients will be evaluated for their clinical response and negativity for Candidiasis. Inclusion criteria: The patients who have oral candidiasis. Exclusion criteria: The patients who unable to provide informed consent, individual may not adhere to treatment and individual may not complete follow up.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201312161059N2**
Registration date: **2014-05-11, 1393/02/21**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2014-05-11, 1393/02/21

Registrant information

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Recruitment status

Recruitment complete

Funding source

Science Medical Vice chancellor for research, Pasteur Institute of Iran

Expected recruitment start date

2014-06-22, 1393/04/01

Expected recruitment end date

2015-02-19, 1393/11/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of Pomegranate peel extract anticandidal activity and nystatin in patients with oral candidiasis

Public title

Efficacy evaluation of pomegranate peel extract in oral candidiasis treatment

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: The patients who have oral candidiasis. Exclusion criteria: The patients who unable to provide informed consent, may not adhere to treatment or may

not complete follow up.

Age
From **1 year** old to **100 years** old

Gender
Both

Phase
0

Groups that have been masked
No information

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features
This randomized clinical trial will be conducted between 22 May 2014 and 19 February 2015, comparing the effectiveness of pomegranate peel extract and nystatin in patients with oral candidiasis. After assessment of eligibility, sixty subjects will be included in this study. After the initial assessment patients by using the random number tables, will be randomly assigned to either an intervention group or a control-group. After randomization by using the random number tables, the two groups of subjects are followed in exactly the same way.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Sciences Ethics committee of Pasteur Institute of Iran

Street address
No. 69,12th Farwardin St., Pasteur St.

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Tehran

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1316943551

Approval date
2013-09-10, 1392/06/19

Ethics committee reference number
92/0110/5333

2

Ethics committee

Name of ethics committee
Ethics committee of Tehran University of Medical Sience, Research institute of Immunology, Asthma &

Street address
No. 62, Dr. Gharib St, Keshavarz Blvd., Immunology, Asthma and Allergy Research Institute, Children's Medical Center, Tehran

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Tehran

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14194

Approval date
2011-12-26, 1390/10/05

Ethics committee reference number
371/412/پ

Health conditions studied

1

Description of health condition studied
Oral Candidiasis

ICD-10 code
B 37.0

ICD-10 code description
Candidal stomatitis/Oral thrush

Primary outcomes

1

Description
Presence of fungal infections

Timepoint
before intervention, one week after intervention and end of intervention

Method of measurement
Clinical examinations of oral lesion, fungal laboratory direct and culture examination of oral lesion

Secondary outcomes

1

Description
presence of side effect

Timepoint
One week and two weeks after intervention

Method of measurement
Clinical examination

Intervention groups

1

Description
Intervention 1: Pomegranate (Punica granatum L.) peel extract gel. The oral gel contains pomegranate peel extract. It will be prepare in Jaber Ebne Hayyan Pharmaceutical Company in 40 ml tubes and it will be use topical three times per day for 14 days. The combination of carbopol and hydroxypropyl methylcellulose will be used as a gel vehicle for pomegranate peel extract topical application.

Category
Treatment - Drugs

2

Description
Intervention 2: Nystatin The nystatin level is 1.72% w/w. The combination of carbopol and hydroxypropyl methylcellulose will be used as a gel vehicle for nystatin topical application. It will be prepare in Jaber Ebne Hayyan Pharmaceutical Company in 40 ml tubes and it will be use topical three times per day for 14 days.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Skin centre of Razi Hospital
Full name of responsible person
Dr Amir Hoshang Ehsani
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Vahdat Eslami Sq., Razi Hospital
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Science Medical Vice chancellor for research, Pasteur Institute of Iran
Full name of responsible person
Dr. Mohammad Ali Shokrgozar
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No. 69, 12th Farwardin St., Pasteur St.
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Tehran
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Science Medical Vice chancellor for research, Pasteur Institute of Iran
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

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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