

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Jul 2026

Comparison of The effective green tea extract with nystatin in denture stomatitis patient

Protocol summary

Summary

Main Objective of the Plan: Study of green tea extraction effect in comparison with nistatin on chronic erythematous candidiasis (denture-induced stomatitis). Secondary Objective of the Plan: Determination of therapeutic effects of green tea on decrease of stomatitis as a result of dentures; Method: This is an open, randomized, controlled, experimental Double Blind Clinical Trial study with 30 patients in two parallel groups, 15 patients will receive nistatin drop and the other ones green tea extract. The patients will be recommended to use mouthwash 4 times a day each time 15-20 drops for 5 min and after that they should prevent from eating and drinking for 30 minutes, and they are suggested to use the drug in two weeks at a specific time. Amount of inflammation and erythema, will be recorded before and after treatment in each session. To determine improvement, we have used two criteria: rating system for density of mycological culture and, erythema surface of palatal mucosa on days 0, 7, 14 after commencement of therapy. After selection of the patients, at each visit, mycological samples will be taken from the palatal mucosa and fitting surface of the denture and will inoculated on Sabouraud's dextrose agar plates. Samples will be taken with sterile cotton swabs and inoculated by rolling the swab over the culture media, then will incubate at 37 °C and after 48hr the colonies will be counted and expressed in terms of densities. At each visit, the erythema of the palatal mucosa will be measured with a graded absLang and will record according to 6-point scale. Method for Preparation of Tea Extraction: Fresh tea leaves were gathered from the farms at North of Iran and transferred immediately to the laboratory and dried in laboratory environment. The dried leaves were milled and the powder was screened to become more uniform and extracted by percolator and hydro-alcoholic solution in 70°, for 24, 48 and 72 hours. The extracted were concentrated by rotary device up to 4.5 in percentage of the dry remaining after filtration.

The extraction, calls mother extraction will be kept in a refrigerator. At the time of prescription and usage of patients, every milliliter of the "mother extraction" will be fined by 5 milliliter of distilled water and prepared in 30 milliliter glasses with dropper for one week of usage by the patients. Considering coefficient of mother extraction fine, the prepared solution is for usage of patients with alcoholic degree of less than 4-5 that will have no effect on the experiment. Inclusion criteria: Those with denture stomatitis lesions in active phase (Diagnostic criteria is the swelling and inflammation below the denture surface); Exclusion criteria: Patients with Diabetes mellitus, Immune deficiency such as acquired immune deficiency syndrome (AIDS), As well as those who will benefit antibacterial drug therapy, corticosteroids, radiotherapy, and smokers will be excluded. Manner of blinding: The drugs shall pour in semi-color and semi-shape glasses and their difference shall be distinguished based on the code and a list, provided to a third person, up to decoding. The examiner and analyzer did not know anything about the drug.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201011052464N2**
Registration date: **2012-07-21, 1391/04/31**
Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2012-07-21, 1391/04/31

Registrant information

Name

Shamsolmolok Najafi

Name of organization / entity

Faculty of Dentistry, Tehran University of Medical

Sciences
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Recruitment status
Recruitment complete
Funding source
Tehran University of Medical Sciences

Expected recruitment start date
2012-07-22, 1391/05/01
Expected recruitment end date
2012-09-22, 1391/07/01
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison of The effective green tea extract with nystatin in denture stomatitis patient

Public title
Green tea extract in the treatment of candidiasis

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria: Those with lesions clinically associated denture stomatitis in the active phase can be reached to confirm an oral specialist (Diagnostic criteria are the swelling and inflammation below the denture surface).
Exclusion criteria: Those who cannot continue to the end of study because of the social or personal reasons; patients with Diabetes mellitus, immune deficiency such as acquired immune deficiency syndrome (AIDS), as well as those who will benefit antibacterial drug therapy, corticosteroids, radiotherapy and smokers will be excluded.

Age
From **40 years** old to **70 years** old

Gender
Both

Phase
2-3

Groups that have been masked
No information

Sample size
Target sample size: **30**

Randomization (investigator's opinion)
Not 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 Tehran University of Medical Sciences

Street address

The End of Amir Abad Street, Enghelab Square

City

Tehran

Postal code

Approval date

2012-06-27, 1391/04/07

Ethics committee reference number

91-01-70-15862-58255

Health conditions studied

1

Description of health condition studied

Chronic Erythematous Candidiasis

ICD-10 code

B37.0

ICD-10 code description

Oral thrush

Primary outcomes

1

Description

Inflammation of the mucosal surface of the denture

Timepoint

On days 0, 7, 14

Method of measurement

By the investigator using graded abslang

2

Description

The number of candida colonies

Timepoint

On days 0, 7, 14

Method of measurement

By culture on Sabouraud's dextrose agar plates

Secondary outcomes

empty

Intervention groups

1

Description

Administration (nistatin)4 times a day, every time (15_20 drops) mouthwash for 5min

Category

Treatment - Drugs

2

Description

The patients will be recommended to use mouthwash 4 times a day each time 15-20 drops for 5 min and after that they should prevent from eating and drinking for 30 minutes, and they are suggested to use the drug in two weeks at a specific time.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Dental School, Tehran University of Medical Sciences

Full name of responsible person

Samira Hajheidary

Street address

End of the Amir Abad Street, Enghelab Square

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Mrs zolfaghari

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keshavarz street blv, Qods Ave-Central Organization of Tehran University of Medical Sciences - 4th Floor

City

Tehran

Grant name

836767

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Tehran 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

Tehran University of Medical Sciences

Full name of responsible person

Samira Hajheidary

Position

Dental student

Other areas of specialty/work

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Person responsible for scientific inquiries

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Shamsolmolok Najafi

Position

Doctor of Dental and Oral Specialist

Other areas of specialty/work

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Person responsible for updating data

Contact

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Full name of responsible person

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Position

Dental student

Other areas of specialty/work

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Web page address**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