Clinical Trial Protocol
Iranian Registry of Clinical Trials

06 Nov 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 nistasin on chronic erythematosus 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 ^{o}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 screed 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 od 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 Erythematosus 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
Street address
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
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Person responsible for scientific inquiries

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Person responsible for updating data

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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