

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Aug 2026

Evaluation the effect of complementary treatment with pistacia atlantica mouthwash on chemotherapy-induced mucositis (a double blind randomized placebo controlled clinical trial)

Protocol summary

Study aim

The main purpose of this study is to evaluate the effect of Pistacia Atlantica mouthwash on reducing severity of mucositis and xerostomia in patients receiving chemotherapy.

Design

In order to design this double blind study we randomly choose 30 patients with cancer (at least 18 years old without allergy to Pistacia Atlantica that not receiving complementary treatments like radiotherapy) receiving chemotherapy in Valie Asr hospital, Zanzan, Iran. Then we divide them into two groups of 15 person, one experimental and one control group.

Settings and conduct

In order to design this study we randomly choose 30 patients with cancer receiving chemotherapy in Valie Asr hospital, Zanzan, Iran. Then we divide them into two groups of 15 person, one experimental and one control group. All the members of both groups have to use MAGIC mouthwash as the basic treatment(3 times a day,each time 10 ml). Members of experimental group have to use Pistacia Atlantica mouthwash and members of control group have to use placebo in addition to that basic treatment (3 times a day,each time 10 ml). Then we evaluate the results of this study by examination of the participates in the first, third and seventh day of the study and re-evaluate them in terms of mucositis severity (using WHO system) and xerostomia severity (using Lickert's method).This study is double blind.(The researcher and participates are blinded)

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1-Existence of chemotherapy-induced mucositis. 2-Participates must be at least 18 years old. 3- Not existence of serious dental problems or traumatic teeth or sharp-pointed cusps or fillings. 4-Not using of traumatic dentures. 5-Not using of anti-inflammatory agents or other mouthwashes during the study. 6-

Absence of other systemic disease. Exclusion criteria: 1- Patients' inability to do the instructions of the protocol of the study. 2-Patients' death because of not responding to the cancer treatment. 3-Complementary treatments such as radiotherapy. 4-The history of allergy to pistacia atlantica. 5-The history of usage of cigarette,narcotics and alcohol.

Intervention groups

In order to design this study we randomly choose 30 patients with cancer receiving chemotherapy in Valie Asr hospital, Zanzan, Iran. Then we divide them into two groups of 15 person, one experimental and one control group. All the members of both groups have to use MAGIC mouthwash as the basic treatment(3 times a day,each time 10 ml). Members of experimental group have to use Pistacia Atlantica mouthwash and members of control group have to use placebo in addition to that basic treatment (3 times a day,each time 10 ml).

Main outcome variables

Oral mucositis intensity in participates using Pistacia Atlantica is different with that in participates using MAGIC mouthwash; Xerostomia intensity in participates using Pistacia Atlantica is different with that in participates using MAGIC mouthwash.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20160731029133N5**

Registration date: **2018-01-30, 1396/11/10**

Registration timing: **registered_while_recruiting**

Last update: **2018-01-30, 1396/11/10**

Update count: **0**

Registration date

2018-01-30, 1396/11/10

Registrant information

Name

Neda Gholami

Name of organization / entity

Zanjan University of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 21 7770 1401

Email address

dr.gholami.n@zums.ac.ir

Recruitment status

Recruitment complete

Funding source

Zanjan University of Medical Sciences

Expected recruitment start date

2018-01-04, 1396/10/14

Expected recruitment end date

2018-02-03, 1396/11/14

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation the effect of complementary treatment with pistacia atlantica mouthwash on chemotherapy-induced mucositis (a double blind randomized placebo controlled clinical trial)

Public title

Evaluation the effect of complementary treatment with pistacia atlantica mouthwash on chemotherapy-induced mucositis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

1-Existence of chemotherapy-induced mucositis. 2- Participates must be at least 18 years old. 3-Not existence of serious dental problems or traumatic teeth or sharp-pointed cusps or fillings. 4-Not using of traumatic dentures. 5-Not using of anti-inflammatory agents or other mouthwashes during the study. 6- Absence of other systemic disease

Exclusion criteria:

1-Patients' inability to do the instructions of the protocol of the study. 2-Patients' death because of not responding to the cancer treatment. 3-Complementary treatments such as radiotherapy. 4-The history of allergy to pistacia atlantica. 5-The history of usage of cigarette,narcotics and alcohol.

Age

From **18 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

We use Block Randomization with individual units in this study and we use sealed envelopes as randomization tool.

Blinding (investigator's opinion)

Double blinded

Blinding description

This is a double blind study.actually the researcher and the participates aren't aware of the grouping randomization process.In order to blind the researcher,instead of the researcher,one of the hospital doctors will put each participate into one of two groups randomly; and in order to blind participates we try to make the mouthwash and the placebo taste the same and prescribe in similar bottles.

Placebo

Used

Assignment

Parallel

Other design features

All the members of both groups have to use MAGIC mouthwash as the basic treatment.This mouthwash consists of: Aluminum-magnesium suspension 200 ml,Diphenhydramine Syrup 50 ml,One Lidocaine carpule,One Dexamethasone ampule,and a bottle of Nystatine.All the members of both groups have to gargle 10 ml of this mouthwash 30 seconds,3 times a day for 7 days.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Zanjan University of Medical Sciences

Street address

Zanjan University of Medical Sciences, Azadi Square

City

Zanjan

Province

Zanjan

Postal code

4515613191

Approval date

2017-08-22, 1396/05/31

Ethics committee reference number

IR.ZUMS.REC.1396.137

Health conditions studied

1

Description of health condition studied

chemotherapy-induced mucositis

ICD-10 code

K12.3

ICD-10 code description

Oral mucositis (ulcerative)

2

Description of health condition studied

Xerostomia

ICD-10 code

K11.7

ICD-10 code description

Disturbances of salivary secretion

Primary outcomes

1

Description

Severity of oral mucositis

Timepoint

Before intervention, 3 days after beginning of the intervention, 7 days after beginning of the intervention(the last day of the intervention)

Method of measurement

WHO scoring system

2

Description

Severity of xerostomia

Timepoint

Before intervention, 3 days after beginning of the intervention, 7 days after beginning of the intervention(the last day of the intervention)

Method of measurement

Lickert's method

Secondary outcomes

empty

Intervention groups

1

Description

The members of the experimental group have to use Pistacia Atlantica mouthwash in addition to that basic treatment.This mouthwsh consists of: Humectant 5-20%(Glycerine-Sorbitol- propylene glycol),Surfactant 5%(Tween80 and sodium lauryl sulfate),a small am

Category

Treatment - Drugs

2

Description

The members of the control group have to use placebo in addition to basic treatment,to eliminate mental effects.(However they shoudn't know that this mouthwash is just a placebo.) Placebo consists of flavoring agents and water.the members of the control

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Vali Asr hospital

Full name of responsible person

Dr. Zahra Abbaspour Rad, Internist, Assisstant Professor

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valiasr squire

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Zanjan University of Medical Sciences

Full name of responsible person

Dr. Neda Gholami

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Zanjan Faculty of Dentistry, Shahrak Karmandan

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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

Zanjan 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**

Zanjan University of Medical Sciences

Full name of responsible person

Dr. Neda Gholami

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work**Street address**

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Full name of responsible person

Yasaman Karbalaee

Position

Dentistry student

Latest degree

A Level or less

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Zanjan

Province

Zanjan

Postal code

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Phone**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

Yes - There is 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

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document

All datas will be published after blinding

When the data will become available and for how long

2 m after publishing the results

To whom data/document is available

researchers working in scientific centers

Under which criteria data/document could be used

datas can be use for furture analysis

From where data/document is obtainable

zanjan dental school

What processes are involved for a request to access data/document

1- written request to research center 2- evaluation in research council. 3- 1 month

Comments