Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Evaluation of the effect of Morus nigra mouthwash on chemotherapy induced oral mucositis

Protocol summary

Summary

The goal of this clinical trial is the evaluation of effect of Morus nigra mouthwash on prevention and reduction of chemotherapy induced oral mucositis rate. This is a randomized double-blind and placebo-control study. 54 patients with Gastrointestinal cancer and under the chemotherapy regimen who are referred to Imam Khomeini hospital and Bagheban medical center in Sari are randomly placed in 2 groups of 27 people (intervention and control group). The first group of patients receive Morus nigra mouthwash three times a day each in the amount of 10 cc for two weeks.The second group receive placebo. All patients are visited at first and then at the end of the first week and the second by oral diseases speciallist and oral mucositis is recorded according to WHO indices.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017070234857N1**
Registration date: **2017-08-03, 1396/05/12**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2017-08-03, 1396/05/12

Registrant information

Name
Anahita Ghorbani
Name of organization / entity
Mazandaran University of Medical Sciences
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Iran (Islamic Republic of)
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+98 911 151 3085
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aghorbani@mazums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellar for research, Mazandaran University of Medical Sciences

Expected recruitment start date

2017-08-06, 1396/05/15

Expected recruitment end date

2017-09-21, 1396/06/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effect of Morus nigra mouthwash on chemotherapy induced oral mucositis

Public title

The effect of Morus nigra mouthwash on mucositis

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria :full awareness; oral mucosal health; non-autoimmune diseases; non-use of drugs; alcohol; cigarettes ; other oral mucus solutions during research and non-treatments such as radiation therapy. exclusion criteria: Do not cooperate with the patient in using mouthwash

Age

No age limit

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **54**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Randomization of samples will take place through a random number table.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Mazandaran University of Medical Sciences

Street address

Vice chancellor for research, the Shahid Motahari Square, Moalem Street

City

Sari

Postal code

-

Approval date

2017-07-09, 1396/04/18

Ethics committee reference number

IR.MAZUMS.REC.96.2979

Health conditions studied

1

Description of health condition studied

Chemotherapy-induced oral mucositis

ICD-10 code

K12.3

ICD-10 code description

Oral mucositis (ulcerative)

Primary outcomes

1

Description

severity of oral mucositis

Timepoint

Before the intervention, one week after the intervention, two weeks after the intervention

Method of measurement

WHO indices

Secondary outcomes

1

Description

-

Timepoint

-

Method of measurement

-

Intervention groups

1

Description

intervention gourp: administration of Morus nigra mouthwash, three times a day up two weeks, each time at 10 cc

Category

Treatment - Drugs

2

Description

Control group: receives placebo

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Khomeini Hospital

Full name of responsible person

Zahra Ghasemzadeh

Street address

Amirmazandarani street, Sari

City

Sari

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Mazandaran University of Medical Sciences

Full name of responsible person

Ahmad Ali Enayati

Street address

Vice chancellor for research, the Shahid Motahari Square, Moalem Street

City

Sari

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice chancellor for research, Mazandaran 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

Sari Dentistry College

Full name of responsible person

Zahra Ghasemzadeh

Position

student of PHD general dentistry

Other areas of specialty/work

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Oral Diseases Specialist- Assistant Professor

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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