Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Comparison of the herbal mouthwash containing Syzygium aromaticum and Commiphora molmol with protact on the improvement of first and Second grade of Chemotherapy-induced mucositis

Protocol summary

Study aim
Efficacy and safety of herbal mouthwash containing Syzygium aromaticum (L.) Merr. & L.M. Perry and Commiphora molmol (Nees) Engl. on Chemotherapy-induced mucositis
Design
Randomized double-blind trial with a control group
Settings and conduct
Emam Khomeini Hospital, Comprehensive cancer center and Touba superficiality clinic
Participants/Inclusion and exclusion criteria
Inclusion Criteria: 1. Age over 18 years 2. Willing to provide written consent form 3. Grade 1 or 2 of chemotherapy-induced mucositis
Intervention groups
One group will receive mouthwash containing Syzygium aromaticum (L.) and Commiphora molmol and another group will receive protact mouth wash 5 ml three times a day. Intervention will continue until improvement of mucositis or until maximum 10 days after initiation of the treatment.
Main outcome variables
Patients' mucositis and pain severity at baseline (day 1) and then days 3, 5, 7 and 10 based on CTCAT (Common Terminology Criteria for Adverse Events) v5-2017 and World Health Organization (WHO) criteria Evaluations will be evaluated.

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20090613002027N19**
Registration date: **2020-02-08, 1398/11/19**
Registration timing: **registered_while_recruiting**
Last update: **2020-02-08, 1398/11/19**
Update count: **0**
Registration date
2020-02-08, 1398/11/19

Registrant information
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Ebrahim Salehifar
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Mazandaran University of Medical Sciences
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2020-02-04, 1398/11/15
Expected recruitment end date
2021-03-19, 1399/12/29
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison of the herbal mouthwash containing Syzygium aromaticum and Commiphora molmol with protact on the improvement of first and Second grade of Chemotherapy-induced mucositis

Public title
Comparison of the herbal mouthwash containing

Syzygium aromaticum and Commiphora molmol with protact on the chemotherapy-induced mucositis

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Age ≥18 years of age Willing to provide written informed consent First and second grade of chemotherapy-induced mucositis

Exclusion criteria:

Age
From **18 years** old

Gender
Both

Phase
2

Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **40**

Randomization (investigator's opinion)
Randomized

Randomization description
For allocation concealment, a 5 numbers digital code obtained from Excel software will be assigned for each patient. Participants will be randomly assigned to the study groups according to block randomization with 4 patients in each block. Random allocation software will be used for block randomization.

Blinding (investigator's opinion)
Double blinded

Blinding description
For wearing groups A and B, instead of labels A or B, each participant will be assigned a random five-digit code that will be taken from the computer.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of mazandaran University of Medical Sciences

Street address
mazandaran university of medical science, darya road, sari

City
sari

Province
Mazandaran

Postal code
4815733971

Approval date
2019-11-09, 1398/08/18

Ethics committee reference number
IR.MAZUMS.REC.1398.1122

Health conditions studied

1

Description of health condition studied
Cancer patients undergoing chemotherapy

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Primary outcome measures included improvement or termination of mucositis

Timepoint
At the beginning of treatment (day 1) and then on days 3, 5, 7 and 10

Method of measurement
Mucositis severity based on Common Terminology Criteria for Adverse Events and World Health Organization Criteria

Secondary outcomes

1

Description
Pain severity

Timepoint
Days 1, 3, 5, 7, 10

Method of measurement
Based on the pain severity according to Visual Analogue Scale

Intervention groups

1

Description
Intervention group: The mouthwash containing Syzygium aromaticum (5%) and Commiphora molmol (5%) 5 ml three times a day

Category
Treatment - Drugs

2

Description
Control group: The protact mouthwash 5 ml three times

a day

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Comprehensive Cancer Center, Emam Khomeini hospital, Sari

Full name of responsible person

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Amir Mazandarani Boulevard

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2

Recruitment center

Name of recruitment center

Touba Clinic

Full name of responsible person

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Khazar sq, Valliasr Blvd

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mazandaran University of Medical Sciences

Full name of responsible person

Dr Majid Saeedi

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Vice chancellor for research of Mazandaran University of Medical Sciences, Moallem Square

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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

Sari 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

Mazandaran University of Medical Sciences

Full name of responsible person

Ebrahim salehifar

Position

Professor

Latest degree

Specialist

Other areas of specialty/work

Medical Pharmacy

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD
Confidentiality of patients data

Study Protocol
No - There is not a plan to make this available

Statistical Analysis Plan
No - There is not a plan to make this available

Informed Consent Form
No - There is not a plan to make this available

Clinical Study Report
No - There is not a plan to make this available

Analytic Code
No - There is not a plan to make this available

Data Dictionary
No - There is not a plan to make this available