Clinical Trial Protocol
Iranian Registry of Clinical Trials

06 Nov 2026

Evaluation of the effectiveness of Zataria multiflora extract mouthwash on prevention of chemotherapy induced oral mucositis In patients undergoing chemotherapy

Protocol summary

Study aim
Determining the effect of Zataria multiflora extract mouthwash on prevention of chemotherapy induced oral mucositis

Design
A double-blinded randomized clinical trial study with parallel groups (intervention group and control group), phases 3 on 78 patients.Randomization will be done according to block randomization method using R software.

Settings and conduct
Based on the inclusion criteria, 78 samples from Iran Mehr Birjand Hospital patients will be selected and randomly divided into two groups of intervention and control. From the first day of the study, the intervention group will receive mouthwash containing Zataria Multiflora and the control group will receive the placebo. All the patients will undergo an oral examination on days 0, 7, 14 and 21 to check the severity of mucositis (according to World Health Organization scale), pain and the incidence time of mucositis.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Chemotherapy is indicated, Age should be between 20 and 70 years, Be alert and able to use mouthwash, The chemotherapy regimen should contain 5-fluorouracil. Exclusion criteria: The presence of traumatizing teeth or traumatizing dentures, Receiving radiotherapy in addition to chemotherapy, Pregnancy or breastfeeding.

Intervention groups
The intervention group receives Protect mouthwash containing Zataria Multiflora (Zolang Respina pharmaceutical company) and the control group receives placebo.

Main outcome variables
Mucositis grade, Mucositis incidence time

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20231126060189N1**
Registration date: **2024-01-23, 1402/11/03**
Registration timing: **prospective**

Last update: **2024-01-23, 1402/11/03**
Update count: **0**

Registration date
2024-01-23, 1402/11/03

Registrant information

Name
Nafiseh Taheri bojd

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 56 3238 1718

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2024-02-19, 1402/11/30

Expected recruitment end date
2024-03-05, 1402/12/15

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Evaluation of the effectiveness of Zataria multiflora extract mouthwash on prevention of chemotherapy induced oral mucositis In patients undergoing chemotherapy

Public title
Evaluation of the effect of Zataria multiflora extract mouthwash on prevention of chemotherapy induced oral mucositis

Purpose
Prevention

Inclusion/Exclusion criteria

Inclusion criteria:
Chemotherapy is indicated Age should be between 20 and 70 years Be alert and able to use mouthwash The chemotherapy regimen should contain 5-fluorouracil

Exclusion criteria:
The presence of traumatizing teeth or traumatizing dentures Receiving radiotherapy in addition to chemotherapy Pregnancy or breastfeeding

Age
From **20 years** old to **70 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor

Sample size
Target sample size: **78**

Randomization (investigator's opinion)
Randomized

Randomization description
Block randomization. After sampling, using "R" statistical software, individuals without clustering are placed in the placebo and intervention groups through block randomization with block size of 8, so that the size of the two groups is equal.

Blinding (investigator's opinion)
Double blinded

Blinding description
A person outside the study codes the mouthwash and placebo, and a code is assigned to each patient. Until the end of the study, the researcher,the evaluator and the participants will not know in which category they have been placed. The placebo contains all the ingredients of intervention mouthwash except Zataria multiflora. The placebo will be the same color as the intervention mouthwash and will be odorless. The packaging of placebo and intervention mouthwash will be the same.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Research Ethics Committee of Birjand University of Medical Sciences

Street address
Ghaffari Ave , birjand university of medical science

City
Birjand

Province
South Khorasan

Postal code
9717853577

Approval date
2023-10-23, 1402/08/01

Ethics committee reference number
IR.BUMS.REC.1402.328

Health conditions studied

1

Description of health condition studied
chemotherapy induced oral mucositis

ICD-10 code
K12.31

ICD-10 code description
Oral mucositis (ulcerative) due to antineoplastic therapy

Primary outcomes

1

Description
Mucositis grade

Timepoint
Days 0, 7, 14 and 21 after starting cancer treatment

Method of measurement
Clinical examination by a dentist based on World Health Organization oral mucositis grading scale.

Secondary outcomes

1

Description
Pain index

Timepoint
Days 0, 7, 14 and 21 after starting cancer treatment

Method of measurement
Visual Analogue Scale and McGill Pain Questionnaire

2

Description

Mucositis incidence time

Timepoint

Days 0, 7, 14 and 21 after starting cancer treatment

Method of measurement

Weekly clinical examination by a dentist

Intervention groups

1

Description

Intervention group: For 21 days, three times a day and half an hour before chemotherapy, they gargle 5 ml of Protect containing Zataria Multiflora(Zulang Respina Pharmaceutical Company) mouthwash for 1 minute.

Category

Treatment - Drugs

2

Description

Control group: Intervention group: For 21 days, three times a day and half an hour before chemotherapy, they gargle 5 ml of placebo mouthwash for 1 minute.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Iranmehr Hospital

Full name of responsible person

Mohamad Amir Mohamadifard

Street address

Ghaffari, Iran Mehr Hospital

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Birjand University of Medical Sciences

Full name of responsible person

Toba Kazemi

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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

Birjand 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

Birjand University of Medical Sciences

Full name of responsible person

Mohamad Amir Mohamadifard

Position

Associate professor

Latest degree

Subspecialist

Other areas of specialty/work

Hematology

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Person responsible for scientific inquiries

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Person responsible for updating data

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Position

Dental student

Latest degree

A Level or less

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be 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

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

Clinical Study Report

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

Analytic Code

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

Data Dictionary

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