

Clinical Trial Protocol

Iranian Registry of Clinical Trials

23 Oct 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)

Phone

+98 56 3238 1718

Email address

nafiseh.taheri.bojd@bums.ac.ir

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
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Birjand University of Medical Sciences
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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
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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