Clinical Trial Protocol
Iranian Registry of Clinical Trials

11 Jul 2026

Randomized clinical trial of the effectiveness of timolol mouthwash to prevention chemotherapy-induced mucositis

Protocol summary

Study aim
Determining the effect of thymolol mouthwash in the prevention of oral mucositis caused by chemotherapy

Design
Patients in two groups receiving Timolol 5% mouthwash or placebo will be randomly divided into reciprocating blocks (each group of 15 people) and each patient will use mouthwashes belonging to their group 3 times a day for 6 weeks. Patients will not use other therapies during this time. This is a forward-looking, two-way blind study of randomized controlled clinical trial and will be performed on 30 patients who accidentally enter two groups of 15 people to control or intervention.

Settings and conduct
Patients admitted to the study will be selected from the clients of the chemotherapy department of Shahid Sadoughi Hospital in Yazd and will enter the study at random.

Participants/Inclusion and exclusion criteria
Conditions for entering the study: all patients over 18 years of age who are being treated with chemotherapy. Adequate literacy to fill the consent form, comprehension study, drug use, pain reporting and possible side effects. Conditions for leaving the study: intolerance to medication; not using mouthwash properly. People with a history of bradycardia.

Intervention groups
They receive a 5% thymol oral mouthwash and a placebo mouthwash control group

Main outcome variables
Clinical presentation; intensity of mucositis and intensity of pain

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20190810044500N9**
Registration date: **2021-01-09, 1399/10/20**
Registration timing: **registered_while_recruiting**

Last update: **2021-01-09, 1399/10/20**
Update count: **0**

Registration date
2021-01-09, 1399/10/20

Registrant information
Name
Fatemeh Saghafi
Name of organization / entity
Country
Iran (Islamic Republic of)
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+98 35 3820 3419
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f.saghafi@ssu.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-10-09, 1399/07/18

Expected recruitment end date
2021-05-08, 1400/02/18

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Randomized clinical trial of the effectiveness of timolol mouthwash to prevention chemotherapy-induced mucositis

Public title
Effectiveness of timolol mouthwash to prevention

chemotherapy-induced mucositis

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

All patients over 18 years of age undergo chemotherapy Adequate literacy to fill out a consent form, understand the study, use the drug, report pain and possible side effects

Exclusion criteria:

Intolerance to medication, misuse of mouthwash People with a history of bradycardia

Age

From **18 years** old

Gender

Both

Phase

2

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients were randomly assigned to two groups of 15 controls or intervention by permutation block method. Treatment assignments within blocks are determined so that they are random in order but that the desired allocation proportions are achieved exactly within each block. 7 blocks of 4 and a block of two are considered. Generation of random codes using Permuted Block Randomization method will be done with the help of Random allocation software (version 1). The first person who is eligible to enter the study is given number one and likewise the last eligible person is given number 30. By using the software generated table, patients receive each of intervention (A or B). In order to consider blinding in random allocation, the list is given to another person outside the study and using short message service (SMS) before assigning the type of treatment according to the number of eligible people is asked and thus people enter the study.

Blinding (investigator's opinion)

Double blinded

Blinding description

The steps will be covered from the perspective of the patient, the treating physician and the assessors. The first presenter identifies the sequence of assignment of patients according to the order of entry of the patients into the study, and puts the mouthwashes into one-size boxes for patient use and identifies them with A or B codes. The student then delivers the drugs to each individual patient

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Commitee of Shahid Sadoughi University Medical Sciencrs

Street address

Proferssor Hesabi Blvd, Yazd

City

Yazd

Province

Yazd

Postal code

8915173149

Approval date

2020-09-13, 1399/06/23

Ethics committee reference number

IR.SSU.MEDICINE.REC.1399.146

Health conditions studied

1

Description of health condition studied

Chemotherapy-induced mucositis

ICD-10 code

Z51.11

ICD-10 code description

Encounter for antineoplastic chemotherapy

Primary outcomes

1

Description

Clinical presentation

Timepoint

Before starting chemotherapy, after starting chemotherapy every week and finally one week after the end of mouthwash consumption (8 visits in total)

Method of measurement

Oral examination

2

Description

The severity of mucositis

Timepoint

Before starting chemotherapy, after starting chemotherapy every week and finally one week after the end of mouthwash consumption (8 visits in total)

Method of measurement

Oral examination and checklists for WHO in 5 grades

3

Description
The severity of the pain
Timepoint
Before starting chemotherapy, after starting chemotherapy every week and finally one week after the end of mouthwash consumption (8 visits in total)
Method of measurement
Oral examination based on the VAS index

Secondary outcomes

1

Description
Quality of life
Timepoint
End of the study
Method of measurement
According to the questionnaire EORTC QLQ-C30 (version 3)

2

Description
Complications observed
Timepoint
End of the study
Method of measurement
Based on the doctor's observation and the person's statements

Intervention groups

1

Description
Intervention group: patients will take timolol 0.5% in combination with hyaluronic acid 0.25% and xylitol 0.75% mouthwash three times a day for six weeks.
Category
Prevention

2

Description
Control group: patients will take placebo mouthwash three times a day for six weeks.placebo contains hyaluronic acid 0.25% and xylitol 0.75%.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Oncology Department of Shahid Sadoughi Hospital in Yazd
Full name of responsible person
Dr. Hassan Ali Vahedian
Street address
Ibn Sina Street
City
Yazd
Province
Yazd
Postal code
8916886938
Phone
+98 35 3822 4000
Email
Sadoghi-hospital@ssu.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Yazd University of Medical Sciences
Full name of responsible person
Massoud Mirzaei
Street address
Bahonar Ave
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Postal code
8916978477
Phone
+98 35 3146 2056
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mmirzaei@ssu.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
Yazd 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
Yazd University of Medical Sciences
Full name of responsible person
Fatemeh Saghafi
Position

Assistant professor

Latest degree
Ph.D.

Other areas of specialty/work
Medical Pharmacy

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Person responsible for updating data

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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