Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Evaluation of the efficacy of 15% sucralfate mouth wash in the prevention and treatment of 5-fluorouracil induced oral mucositis in cancer patients in sari city

Protocol summary

Summary

Oral mucositis is one of the severe side effects of chemotherapeutic agents which limits their use. The aim of this clinical trial is to evaluate the efficacy of sucralfate mouth wash (15 %) in the prophylaxis and treatment of oral mucositis induced by the chemotherapeutic agent 5-fluorouracil. Trial design: prospective, randomized, double-blind, placebo-controlled clinical trial. Inclusion criteria: cancer patients 18-70 years receiving 5-fluorouracil containing chemotherapy. Exclusion criteria: sucralfate intolerance or inappropriate use of the mouth wash. intervention 1: sucralfate mouth wash four times daily for 1 week. Intervention 2: placebo 4 times daily for 1 week. Intervention 3: sucralfate mouth wash and hydroxyzine syrup 4 times daily for 1 week. Intervention 4: placebo and hydroxyzine syrup 4 times daily for 1 week. Outcomes: 1- oral mucositis, measure: WHO grading system. 2- pain, measure: Visual analogue scale. Measurement time point: every 3 days (days 0 and 3 and 6

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201107053014N4**
Registration date: **2012-04-27, 1391/02/08**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2012-04-27, 1391/02/08

Registrant information

Name

Shahram Ala

Name of organization / entity

Mazandaran University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Mazandaran University of Medical Sciences

Expected recruitment start date

2011-11-01, 1390/08/10

Expected recruitment end date

2012-06-09, 1391/03/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the efficacy of 15% sucralfate mouth wash in the prevention and treatment of 5-fluorouracil induced oral mucositis in cancer patients in sari city

Public title

Evaluation the effect of sucralfate 15% mouthwash for Prevention and treatment mouth sores induced by chemotherapy drugs

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:Cancer patients between 18-70 years

receiving 5-fluorouracil containing chemotherapy regimens. Exclusion criteria: Sucralfate intolerance or inappropriate use of the mouth wash

Age
From **18 years** old to **70 years** old

Gender
Both

Phase
2-3

Groups that have been masked
No information

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee , Mazandaran University of Medical Sciences

Street address
Vice chancellor for research , Moalem Squer , Mazandaran University of Medical Sciences

City
Sari

Postal code

Approval date
2011-07-27, 1390/05/05

Ethics committee reference number
25

Health conditions studied

1

Description of health condition studied
5-fluorouracil induced oral mucositis

ICD-10 code
k00-k14

ICD-10 code description
Disease of oral cavity : stomatitis

Primary outcomes

1

Description
Mouth sores

Timepoint
every 3 days

Method of measurement
Use of the WHO table and ruler

Secondary outcomes

1

Description
Pain

Timepoint
Before and after 1 months of intervention

Method of measurement
Visual analoug scale (VAS)

2

Description
Dysphagia to liquids

Timepoint
Before and after 2 months of intervention

Method of measurement
Ask a question

3

Description
Dysphagia to solids

Timepoint
weekly

Method of measurement
Ask a question

4

Description
Bleeding

Timepoint
Before and after 2 months of intervention

Method of measurement
Ask a question

Intervention groups

1

Description
Sucralfate , mouthwash , 15 percent , four times a day for a week

Category
Prevention

2

Description

Placebo mouthwash , 4 times a day for a week

Category

Placebo

3

Description

Sucralfate 15 percent mouth wash plus syrup Hydroxyzine , four times a day until oral wound healing

Category

Treatment - Drugs

4

Description

Syrup Hydroxyzine plus placebo , four times a day until oral wound healing

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Specialty and subspecialty clinics Tuba

Full name of responsible person

Shahram Ala

Street address

Clinic Tuba, Khazar Squar , Sari , Mazandaran , Iran

City

Sari

2

Recruitment center

Name of recruitment center

Imam Khomeini hospital in Sari

Full name of responsible person

Shahram Ala

Street address

Imam Khomeini Hospital, Amir Mazandarani St., Sari , Mazandaran , Iran

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

Dr. Ahmadali Enayati

Street address

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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

Vice chancellor for research, Mazandaran University of Medical Sciences

Full name of responsible person

Elham Azhdari

Position

Pharmacy student

Other areas of specialty/work

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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