

Clinical Trial Protocol

Iranian Registry of Clinical Trials

13 Jun 2026

Efficacy of Phenytoin mucoadhesive tablet versus mouthwash on chemotherapy induced oral mucositis

Protocol summary

Study aim

evaluating the efficacy of phenytoin mucoadhesive tablets in treating oral mucositis compared with phenytoin mouthwash.

Design

parallel group, randomised controlled clinical trial

Settings and conduct

Patients will be enrolled from the oncology department of Nemazee Hospital, in Shiraz, Iran. Data are gathered by observation and interview. Patients are examined for oral mucositis and are assessed using the WHO grading on a scale of 0–4. Severity of oral pain is evaluated using a visual analogue scale (VAS) scoring 0–10. The extension of lesions is also recorded by the number of involved sites. These examinations are performed at three intervals: prior to the start of the study, one and two weeks after treatment. After examination, the phenytoin mouthwash and mucoadhesive tablet which are prepared by the faculty of Shiraz pharmacy; is delivered to the patient.

Participants/Inclusion and exclusion criteria

The study population consist of patients undergoing chemotherapy process, due to various types of malignancies

Intervention groups

Patients in group A will be instructed to rinse (gargle) 10 ml of the solution for one minute, three times a day (to distribute evenly to all parts of the oral tissues), and then spit. For patients in group B, two tablets should be attached inside the cheek until they are dissolved.

Main outcome variables

the grade of oral mucositis, the number of oral lesions, pain

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20130521013406N5**

Registration date: **2019-07-07, 1398/04/16**

Registration timing: **retrospective**

Last update: **2019-07-07, 1398/04/16**

Update count: **0**

Registration date

2019-07-07, 1398/04/16

Registrant information

Name

Fahimeh Rezazadeh

Name of organization / entity

Dental school of shiraz university of medical science

Country

Iran (Islamic Republic of)

Phone

+98 71 1628 9917

Email address

rezazadehf@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2014-04-21, 1393/02/01

Expected recruitment end date

2014-08-23, 1393/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Efficacy of Phenytoin mucoadhesive tablet versus mouthwash on chemotherapy induced oral mucositis

Public title

Phenytoin Mucoadhesive Tablet versus Mouthwash in treatment of Oral Mucositis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

patients underwent chemotherapy process, due to various types of malignancies, without concurrent radiotherapy mucositis grade 2 or 3 (WHO criteria) prognosis for at least 6 months signing the consent form

Exclusion criteria:

Patients with mucositis of grade 1 or 4 sign of causing side effects (such as sensitivity to phenytoin) lack of patient cooperation or trend to complete the treatment process systemic diseases with oral mucositis (such as connective tissue diseases and Sjogren syndrome) or interfering with healing process of tissues (such as diabetes) smoking and alcohol consumption

Age

No age limit

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: 40

Randomization (investigator's opinion)

Randomized

Randomization description

block randomized study

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shiraz University of Medical Sciences

Street address

Central building of Shiraz University of Medical Sciences Zand St., Shiraz, Iran

City

Shiraz

Province

Fars

Postal code

7134814336

Approval date

2014-04-09, 1393/01/20

Ethics committee reference number

8593063

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

grade of oral mucositis and pain

Timepoint

before intervention, 1 and 2 weeks after intervention

Method of measurement

WHO grading and Visual analogue scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: phenytoin mucoadhesive tablet Mucoadhesive tablets are prepared by direct compression method. The ingredients (10 mg sodium phenytoin and the remaining ingredient was HPMC: Chitosan; NaCMC, 25:25:50 w/w %) are weighed accurately and mixed by trituration in a mortar by pestle for 15 minutes. Then all of the ingredients are passed through sieve no. 100. Finally the mixture is compressed to tablet using Korsch single punch compression machine (ERWEKA, German). Each day, two tablets should be attached inside the cheek until they are dissolved and the treatment should be continued until the complete healing of oral lesions or for a maximum of two weeks.

Category

Treatment - Drugs

2

Description

Intervention group: Phenytoin mouthwash Appropriate amount of sodium phenytoin is dissolved in 1 L of distilled water which contain 0.1% Tween 80 and Disodium hydrogen phosphate (2.38 g/L), with adjusted pH on 7.0 ± 0.02 using phosphoric acid. The final concentration of phenytoin mouthwash is 0.333 mg/mL. patients are instructed to rinse (gargle) 10 ml of the

solution for one minute, three times a day (to distribute evenly to all parts of the oral tissues), and then spit (to minimize the systemic absorption). They are told to avoid eating during the first hour after treatment

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Nemazee hospital

Full name of responsible person

Fahimeh Rezazadeh

Street address

Namazi square, Zand Ave, Shiraz, Fars

City

Shiraz

Province

Fars

Postal code

71936-13311

Phone

+98 71 3647 4332

Fax

+98 71 3647 4326

Email

nemazee_inf@sums.ac.ir

Web page address

<http://namazi.sums.ac.ir/>

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Shiraz University of Medical Sciences

Full name of responsible person

Dr. Gholamreza Hatam

Street address

Shiraz University of Medical Sciences

City

Sshiraz

Province

Fars

Postal code

7134814336

Phone

+98 71 3230 5410

Email

info@sums.ac.ir

Web page address

<https://sums.ac.ir/>

Grant name

no grant

Grant code / Reference number

000000

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Shiraz 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**

Shiraz University of Medical Sciences

Full name of responsible person

Fahimeh Rezazadeh

Position

Assistant professor

Latest degree

Specialist

Other areas of specialty/work

Dentistry

Street address

Shiraz University of Medical Sciences, Zand Ave, Shiraz

City

Shiraz

Province

Fars

Postal code

7134814336

Phone

+98 71 3230 5410

Email

Rezazadehf@sums.ac.ir

Person responsible for scientific inquiries**Contact****Name of organization / entity**

Shiraz University of Medical Sciences

Full name of responsible person

Fahimeh Rezazadeh

Position

Assistant

Latest degree

Specialist

Other areas of specialty/work

Dentistry

Street address

Shiraz University of Medical sciences, Zand Ave, Shiraz

City

Shiraz

Province

Fars
Postal code
7134814336
Phone
+98 71 3230 5410
Email
rezazadehf@sums.ac.ir

Phone
+98 71 3628 9917
Fax
+98 71 1626 3193
Email
rezazadehf@sums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Fahimeh Rezazadeh
Position
Assistant professor
Latest degree
Specialist
Other areas of specialty/work
Dentistry
Street address
oral medicine department, Shiraz Dental School,
Ghasrodasht Ave
City
Shiraz
Province
Fars
Postal code
7195615878

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