

Clinical Trial Protocol

Iranian Registry of Clinical Trials

05 Jun 2026

Evaluation of the effect of niosomal mouth wash Amitriptyline as local anesthetics in patients with oral mucositis due to radio therapy or chemo therapy and comparison with mouth wash Benzylamine HCl

Protocol summary

Summary

(1) Objectives, The aim of this study was to Evaluation of the effect of niosomal mouth wash Amitriptyline as local anesthetics. (2) Design (study groups and phase, sample size, blinding, randomization, single or multi center), 60 persons will be studied. Divided into three groups. (3) Setting and conduct, Each patient is given a mouthwash in double-blind randomization. (4) Participants including major eligibility criteria, Inclusion criteria: having oral mucositis due to radiotherapy or chemotherapy and having pain or burning mouth while study. Excluding criteria: systemic disease or allergic to three-cyclic antidepressants (5) Intervention, To patients, the oral rinse for 30 seconds (mouth wash Amitriptyline and niosomal mouth wash Amitriptyline control: mouth wash Benzylamine HCl) (6) main outcome measures (primary and secondary outcome variables), painless amount will be checked using the VAS form at intervals 1,5,10,30 and 60 minutes.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015112123529N1**

Registration date: **2015-11-21, 1394/08/30**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2015-11-21, 1394/08/30

Registrant information

Name

Elahe Tahmasebi

Name of organization / entity

Kerman university of medical sciences

Country

Iran (Islamic Republic of)

Phone

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Kerman University of Medical Sciences

Expected recruitment start date

2014-03-20, 1392/12/29

Expected recruitment end date

2016-02-14, 1394/11/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effect of niosomal mouth wash Amitriptyline as local anesthetics in patients with oral mucositis due to radio therapy or chemo therapy and comparison with mouth wash Benzylamine HCl

Public title

anesthetics effect of mouth wash Amitriptyline

Purpose

Treatment

Inclusion/Exclusion criteria

inclusion criteria: patients with oral mucositis due to radiotherapy or chemotherapy; having pain or burning mouth while study. exclusion criteria: allergic to three-cyclic antidepressants.

Age

No age limit

Gender

Both

Phase

N/A

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

Not used

Assignment

Parallel

Other design features

sealed envelopes will used to allocation group
randomisation

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Kerman University of Medical
Sciences

Street address

Vice chancellor for research Building, Jihad st.

City

Kerman

Postal code

7617961965

Approval date

2014-09-23, 1393/07/01

Ethics committee reference number

K/93/366

Health conditions studied

1

Description of health condition studied

Anaesthesia

ICD-10 code

F44.6

ICD-10 code description

Dissociative anaesthesia and sensory loss

Primary outcomes

1

Description

severity

Timepoint

befor intervention and in 1, 5, 10, 30 and 60 minutes
after intervention

Method of measurement

VAS form

Secondary outcomes

1

Description

-

Timepoint

-

Method of measurement

-

Intervention groups

1

Description

intervention group1: niosomal mouth wash
Amitriptyline(Manufacturer: Darou Pakhsh
Pharmaceutical Mfg Co.) ,15 cc for 30 seconds qd

Category

Treatment - Drugs

2

Description

intervention group2: mouth wash
Amitriptyline(Manufacturer: Darou Pakhsh
Pharmaceutical Mfg Co.),15 cc for 30 seconds qd

Category

Treatment - Drugs

3

Description

control group: mouth wash Benzydamine
HCl(Manufacturer: Darou Pakhsh Pharmaceutical Mfg
Co.),15 cc for 30 seconds qd

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Oncology dept.of Shafa hospital

Full name of responsible person

Dr. Mohammad Hossein Larizade

Street address

City

Kerman

2

Recruitment center

Name of recruitment center

Oral medicin dept. Dentistry School of Kerman
University of Medical Sciences

Full name of responsible person

DR Elahe Tahmasebi

Street address**City**

Kerman

3

Recruitment center

Name of recruitment center

Hematology dept. of Bahonar Hospital

Full name of responsible person

Dr. Behjat Kalantari

Street address

Bahonar Hospital, Qaraney St.

City

Kerman

4

Recruitment center

Name of recruitment center

Hematology Clinic

Full name of responsible person

Dr. Behjat Kalantari

Street address

Park Clinic Building, Neshat St.

City

Kerman

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Kerman University of
Medical Sciences

Full name of responsible person

Dr. Moolook Torabi

Street address

Dentistry School , Shafa St.

City

Kerman

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, Kerman 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

Kerman University of Medical Sciences

Full name of responsible person

Dr. Elahe Tahmasebi

Position

Oral Medicin Assistant

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Web page address**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