Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 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 Benzydamine 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 Benzydamine HCl) (6) main outcome measures (primary and secondary outcome variables), painless amount will 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
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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 Benzydamine 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
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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
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3

Recruitment center
Name of recruitment center
Hematology dept. of Bahonar Hospital
Full name of responsible person
Dr. Behjat Kalantari
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Bahonar Hospital, Qaraney St.
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4

Recruitment center
Name of recruitment center
Hematology Clinic
Full name of responsible person
Dr. Behjat Kalantari
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Park Clinic Building, Neshat St.
City
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for research, Kerman University of Medical Sciences
Full name of responsible person
Dr. Molook Torabi
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Dentistry School , Shafa St.
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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
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

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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