Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Assessment of formulation of natural honey for the prevention of chemotherapy induced oral mucositis

Protocol summary

Summary

A randomized clinical trial is carried out in order to evaluate the effect of the oral gel based on natural honey for prevention of oral mucositis.80 female patients diagnosed with breast cancer are recruited. Patients should be on chemotherapy regimen wich induce oral mucositis.Enrollment of patients is randomized in four blocking designed to two groups.Group A are patients who are going under chemotherapy treatment with general oral care and rinsing saline is prescribed by the dentist specialized in oral disease and healths,group B are patients whit similar regimen but supplied whit our formulation. Patients are excluded from the investigation in the case of sensitivity or intolerability to our formulation,unwillingness to take apart in the study and developing severe mucositis or other oral complications. Patients will be assessed daily from the first day of treatment by self-assessment questionnaire and WHO grading by researchers and visual examination every two to tree weeks on one to one assessment(visual examination)based on the cycle of chemotherapy. Parameters such as pain,speech,eating solid and semisolid food,drinking,swallowing,taste changes,changes in amount or concentration of saliva,burning,gingival bleeding or discomfort,erythema,soreness,ulcers,unusual colors,infections,the needs of topical or systemic painkillers and duration of mucositis will be assessed and patients are followed for four cycles.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201506063106N25**
Registration date: **2015-06-12, 1394/03/22**
Registration timing: **registered_while_recruiting**
Last update:
Update count: **0**

Registration date

2015-06-12, 1394/03/22

Registrant information

Name
Farshad Hashemian
Name of organization / entity
Pharmaceutical Sciences Branch, Islamic Azad University (IAU)
Country
Iran (Islamic Republic of)
Phone
+98 21 2260 0037
Email address
hashemian.f@iaups.ac.ir

Recruitment status

Recruitment complete

Funding source

1-Pharmaceutical science branch of Islamic Azad University 2- private sponsor

Expected recruitment start date

2015-05-22, 1394/03/01

Expected recruitment end date

2015-09-22, 1394/06/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Assessment of formulation of natural honey for the prevention of chemotherapy induced oral mucositis

Public title

Assessment of natural honey oral gel for the prevention of chemotherapy induced oral sorness

Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria: being adult female diagnosed breast cancer;new patient under chemotherapy regimen wich induce oral mucositis;not pregnant and lactating;have a normal oral cavity examination;no diabetes;no renal and liver disorders;and no sensitivity to active ingrediants. Exclusion criteria: sensitivity or intolerability to the formulation;unwillingness to take apart in study;developing of severe mucositis or acute other oral complications.
Age
From **18 years** old to **70 years** old
Gender
Female

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **80**
Randomization (investigator's opinion)
Randomized
Randomization description
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
Pharmaceutical science branch of Islamic Azad University
Street address
No.99, Yakhchal street, Dr. Shariati Avenue Tehran
City
Tehran
Postal code
1941933111
Approval date
2014-08-17, 1393/05/26
Ethics committee reference number
5936

Health conditions studied

1

Description of health condition studied
Oral mucositis
ICD-10 code
K12.3
ICD-10 code description
Oral Mucositis(ulcerative

Primary outcomes

1

Description
Oral mucositis
Timepoint
Daily and every two or tree weeks
Method of measurement
Self-assessment questionnaire and WHO grading and oral examination

2

Description
Pain in the oral cavity
Timepoint
Daily
Method of measurement
self-assessment questionnaire

3

Description
Speech
Timepoint
Daily
Method of measurement
Self-assessment questionnaire

4

Description
Oral ulcers
Timepoint
Daily and every two or tree weeks
Method of measurement
Self-assessment quesionnaire and WHO grading and oral examination

5

Description
Eating solid and semisolid food
Timepoint
Daily
Method of measurement
Self-assessment questionnaire

6

Description
Saliva changes
Timepoint

Daily

Method of measurement

Self-assessment questionnaire

7

Description

Drinking

Timepoint

Daily

Method of measurement

Self-assessment quesionnaire

8

Description

Swallowing

Timepoint

daily

Method of measurement

Self-assessment questionnaire

9

Description

Taste changes

Timepoint

Daily

Method of measurement

Self-assessment questionnaire

10

Description

Gingival bleeding and discomfort

Timepoint

Daily

Method of measurement

Self-assessment questionnaire

11

Description

Burning in the oral cavity

Timepoint

Daily

Method of measurement

Self-assessment questionnaire

12

Description

Erythema in the oral cavity

Timepoint

Daily

Method of measurement

Self-assessment questionnaire and oral examinaion and WHO grading

13

Description

Unusual color in the oral cavity

Timepoint

Daily

Method of measurement

Self-assessment questionnaire and oral examination and WHO grading

14

Description

Infection in the oral cavity

Timepoint

daily and every two or tree weeks

Method of measurement

Self-assessment questionnaire and oral examination

15

Description

Using pain killer for oral complications

Timepoint

daily

Method of measurement

Self-assessment questionnaire

16

Description

Duration of mucositis

Timepoint

Every two or tree weeks

Method of measurement

Self-assessment questionnaire

Secondary outcomes

1

Description

Investigational product side effects

Timepoint

Every two or tree weeks

Method of measurement

Self-assessment questionnaire

Intervention groups

1

Description

interventional group: are patients whit similar protocol for control group(the oral care and rinsing normal saline)but supplied whit our formulation two to four times a day from the first day of study till the last day of fourth cycle of following.

Category

Prevention

2

Description

Control group are patients whit the oral care and rinsing salin that prescribed by the dentist specialized in oral deases and healths.

Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
Cancer institue of Imam Khomeini hospital
Full name of responsible person
Dr. Mehdi Rajabi
Street address
Pharmaceutical science branch of Islamic Azad University
City
Tehran

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Pharmaceutical science branch of Islamic Azad University
Full name of responsible person
Dr. Sepideh Arbabi Bidgoli
Street address
No.99, Yakhchal street, Dr. Shariati Avenue Tehran
City
Tehran
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Pharmaceutical science branch of Islamic Azad University
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
Pharmaceutical science branch of Islamic Azad university
Full name of responsible person
Dr. Mehdi Rajabi
Position
Assistant professor / Head of Department
Other areas of specialty/work
Street address
No.99, Yakhchal street, Dr. Shariati Avenue
City
Tehran
Postal code
Phone
+98 21 2246 0056
Fax
Email
mehdirj@aol.co.uk
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
Pharmaceutical science branch of Islamic Azad university
Full name of responsible person
Dr. Mehdi Rajabi
Position
Assistant professor / Head of Department
Other areas of specialty/work
Street address
No.99, Yakhchal street, Dr. Shariati Avenue
City
Tehran
Postal code
Phone
+98 21 2246 0056
Fax
Email
mehdirj@aol.co.uk
Web page address

Person responsible for updating data

Contact
Name of organization / entity
Pharmaceutical Sciences Branch,Islamic Azad University(IAU)
Full name of responsible person
Elnaz Jahanbani Mazraeh
Position
Pharmacist
Other areas of specialty/work
Street address
No 4,Shifteh alley,Hedayat street,Darrous
City
Tehran
Postal code
Phone
00
Fax
Email
elnaz.jahanbani@yahoo.com
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