

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

05 Jun 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 which 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 health, group B are patients with similar regimen but supplied with our formulation. Patients are excluded from the investigation in the case of sensitivity or intolerance to our formulation, unwillingness to take part 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 three 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)

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###### Email address

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##### 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 soreness

## 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 questionnaire 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 questionnaire

**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 examination 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 three 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 three weeks

**Method of measurement**

Self-assessment questionnaire

**Secondary outcomes**

**1**

**Description**

Investigational product side effects

**Timepoint**

Every two or three weeks

**Method of measurement**

Self-assessment questionnaire

**Intervention groups**

**1**

**Description**

interventional group: are patients with similar protocol for control group (the oral care and rinsing normal saline) but supplied with 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 with the oral care and rinsing saline that prescribed by the dentist specialized in oral diseases and healths.

**Category**

Prevention

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

Cancer institute 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**

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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**

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**

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**Full name of responsible person**

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Assistant professor / Head of Department

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**Full name of responsible person**

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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*