

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

26 May 2026

### The effect of Glutamine Oral gel on prevention of chemotherapy-induced mucositis

#### Protocol summary

##### Summary

Oral mucositis is a common complication of many cancer treatments that has an adverse impact on the quality of life of patient. It is characterized by painful erythematous and ulcerative lesions. When Glutamine is administered via oral drug delivery, it can reduce oral mucositis, however, not significant as it has low solubility and absorption. The purpose of this study was to evaluate the local effect of glutamine oral gel in prevention of oral mucositis. A randomized clinical trial was carried out in order to evaluate the effect of glutamine oral gel for prevention of oral mucositis. 50 diagnosed cancer patients were recruited. All patients were on main chemotherapeutic agents which are associated with oral mucositis as a main side effect. Patients were divided into two groups of 25. Group A are patients who are going under chemotherapy treatment with general oral care, group B are patients with similar regimen but supplied with glutamine oral gel. Patients were assessed at baseline and at the end of each cycle using visual examination as well as using the Patient-Reported Oral Mucositis Symptom (PROMS) scale and Oral Mucositis Assessment Scale (OMAS) questionnaires. Patients were followed for a period of three cycles.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201411153106N19**  
Registration date: **2014-12-12, 1393/09/21**  
Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2014-12-12, 1393/09/21

#### 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

Islamic Azad University, pharmaceutical sciences branch

#### Expected recruitment start date

2014-11-22, 1393/09/01

#### Expected recruitment end date

2015-02-20, 1393/12/01

#### Actual recruitment start date

empty

#### Actual recruitment end date

empty

#### Trial completion date

empty

#### Scientific title

The effect of Glutamine Oral gel on prevention of chemotherapy-induced mucositis

#### Public title

The effect of Glutamine Oral gel on prevention of chemotherapy-induced mucositis

#### Purpose

Prevention

#### Inclusion/Exclusion criteria

Inclusion criteria: consciousness; being literate; chemotherapeutic management with drugs which induce mucositis; no stomatitis; no oral disease; no renal & liver

disorders; no auto immune disease and diabetes; no fever and neutropenia; no received antibiotic & narcotic analgesic Exclusion criterion: sensitivity to glutamine oral gel.

#### Age

From **20 years** old to **75 years** old

#### Gender

Both

#### Phase

N/A

#### Groups that have been masked

*No information*

#### Sample size

Target sample size: **50**

#### 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

IAUPS branch of pharmaceutical sciences

##### Street address

pharmaceutical sciences branch, Islamic AZAD university, Yakhchal street, Shariati street

##### City

Tehran

##### Postal code

1941933111

#### Approval date

2013-12-31, 1392/10/10

#### Ethics committee reference number

4857

## 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

Mucositis

#### Timepoint

At the end of cycle for 3 cycles

#### Method of measurement

PROMS and OMAS questionnaires

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: general oral care with glutamine oral gel, from the first day up the end of cycle for 3 cycles. Patients were assessed at baseline and at the end of each cycle using visual examination as well as using the Patient-Reported Oral Mucositis Symptom (PROMS) scale and Oral Mucositis Assessment Scale (OMAS) questionnaires

#### Category

Treatment - Drugs

### 2

#### Description

Control group: general oral care

#### Category

N/A

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Taleghani hospital

##### Full name of responsible person

Dr. Abdolali Shahrasbi

##### Street address

##### 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**

### **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

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Tehran

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+98 21 2246 0056

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mehdirj@aol.co.uk

**Web page address**

### **Person responsible for updating data**

**Contact**

### **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*