

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Evaluation the effect of azithromycin oral suspension on the prevention and treatment of mucositis in Hematopoietic Stem Cell Transplant recipients

#### Protocol summary

##### Summary

The aim of this study is to evaluate the effect of oral suspension azithromycin on chemotherapy induced mucositis. Inclusion criteria included patients undergoing bone marrow transplantation is satisfactory and exclusion criteria azithromycin drug allergy or lack of patient satisfaction. The study population of patients undergoing bone marrow transplantation Taleghani Hospital and the sample size of 60 is considered. Intervention effect of azithromycin drug prevention and treatment of mucositis patients in this study lists the Persian date Bahman 1394 to Persian date Bahman 1396.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201603093210N13**  
Registration date: **2017-02-09, 1395/11/21**  
Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2017-02-09, 1395/11/21

##### Registrant information

###### Name

Maria Tavakoli Ardakani

###### Name of organization / entity

Faculty of pharmacy, Shaid Beheshti University of  
Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 21 8887 3704

##### Email address

mariatavakoli@sbmu.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

School of pharmacy, Shahid Beheshti University of  
Medical Sciences

##### Expected recruitment start date

2015-12-31, 1394/10/10

##### Expected recruitment end date

2017-12-31, 1396/10/10

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Evaluation the effect of azithromycin oral suspension on  
the prevention and treatment of mucositis in  
Hematopoietic Stem Cell Transplant recipients

##### Public title

Evaluation the effect of azithromycin oral suspension on  
the mucositis in patients undergoing Hematopoietic Stem  
Cell Transplantation

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

Inclusion criteria: All patients hospitalized in bone  
marrow transplantation and patients undergoing  
chemotherapy; Patients satisfaction to participate in the  
study The exclusion criteria: Unwillingness of patients to  
continue; Allergic reactions to medication or other  
subunits of mouthwash

##### Age

From **12 years** old to **70 years** old

## 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

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics Committee of the Faculty of Pharmacy,  
University shahid Beheshti

##### Street address

niyayesh.vali-asr

##### City

tehran

##### Postal code

#### Approval date

2010-09-23, 1389/07/01

#### Ethics committee reference number

IR.SBMU.PHNM.1394.307

## Health conditions studied

### 1

#### Description of health condition studied

- C00-D49 Neoplasms

#### ICD-10 code

#### ICD-10 code description

## Primary outcomes

### 1

#### Description

mucositis

#### Timepoint

first day of chemotherapy until engraftment day

#### Method of measurement

WHO scoring system

## Secondary outcomes

### 1

#### Description

fever grade

#### Timepoint

From the first day of chemotherapy until engraftment time

#### Method of measurement

Submit a fever above 38.5 ° C for patients

### 2

#### Description

The need for total parenteral nutrition (TPN)

#### Timepoint

During the study period

#### Method of measurement

Sign the days of parenteral nutrition intake

## Intervention groups

### 1

#### Description

Azithromycin oral suspension 300mg twice daily from first day of chemotherapy until engraftment day plus standard supportive care for mucositis in intervention group versus standard care of mucositis in control group.

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

the bone marrow transplantation department of taleghani hospital

##### Full name of responsible person

##### Street address

##### City

tehran

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Maria Tavakoli-Ardakani

##### Full name of responsible person

00989121863686

##### Street address

Vali-e Asr Ave, Niayesh Junction

##### City

Tehran

#### Grant name

#### Grant code / Reference number

**Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Maria Tavakoli-Ardakani

**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**

Students Research committee, School of pharmacy,  
Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Mohadeseh Zeraatkar

**Position**

Pharm D student

**Other areas of specialty/work****Street address**

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**City**

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**Web page address****Person responsible for scientific inquiries****Contact****Name of organization / entity**

clinical pharmacy department, school of pharmacy &  
pharmaceutical sciences research center, Shahid B

**Full name of responsible person**

Maria Tavakoli-Ardakani

**Position**

Associate professor

**Other areas of specialty/work****Street address**

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Tehran

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**Web page address****Person responsible for updating data****Contact****Name of organization / entity****Full name of responsible person**

Mohadeseh Zeraatkar

**Position****Other areas of specialty/work****Street address****City****Postal code****Phone**

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**Fax****Email****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*