Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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

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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 fortotal parenteral nutrition(TPN)
Timepoint
During the study period
Method of measurement
SignTthe daysof 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 transplantasion departmant 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
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Students Research committee, School of pharmacy, Shahid Beheshti University of Medical Sciences
Full name of responsible person
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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
00
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