

Clinical Trial Protocol

Iranian Registry of Clinical Trials

07 Jun 2026

The effect of zinc gluconate mouthwash in prevention of mucositis , following the administration of high doses of methotrexate in children with acute lymphoblastic leukemia

Protocol summary

Study aim

The effect of zinc gluconate in prevention of mucositis, following a high dose of methotrexate in children with acute lymphoblastic leukemia

Design

Clinical trial with control group, double-blind and randomized

Settings and conduct

Patients with acute lymphoblastic leukemia who are admitted to the pediatric oncology ward and are being treated with a high dose of methotrexate. For the patient, mouthwash should be performed every 8 hours from the start of the 24-hour methotrexate infusion and kept in the mouth for at least 30 seconds. In the intervention group, 1 mg zinc gluconate is added to the above solution. The studied patients and the design dentist who is in charge of the post-treatment examination are not aware of the type of mouthwash used in each patient-episode

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age of 5 to 15 years, ALL, treated by high dose of methotrexate, no mucositis before receiving methotrexate, no nausea and vomiting before starting methotrexate exclusion criteria: presence of fever, use of systemic or topical antibiotics

Intervention groups

Patients from 5 to 10 years old children with ALL who are treated with a high dose of intravenous methotrexate (5 g / 24 hours infusion). In the control group, the patient receives a standardized oral mucosa (containing 100,000 units nystatin per cc + diphenhydramine 2.5 mg per cc + 260 cc MG aluminum syrup). The case group in each patient-the mouthpiece episode in the same container containing the above plus 1grams in cc of zinc gluconate is used similarly.

Main outcome variables

The presence of mucositis, Mucositis intensity, Mucositis

period, Number of nausea, The number of vomiting times, Number of feeds of fluids, The frequency of feeding solids

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190202042583N3**

Registration date: **2021-09-01, 1400/06/10**

Registration timing: **retrospective**

Last update: **2021-09-01, 1400/06/10**

Update count: **0**

Registration date

2021-09-01, 1400/06/10

Registrant information

Name

Mohammad Naderisorki

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 11 3334 7837

Email address

dr.naderisorki@mazums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-06-22, 1398/04/01

Expected recruitment end date

2020-06-21, 1399/04/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of zinc gluconate mouthwash in prevention of mucositis , following the administration of high doses of methotrexate in children with acute lymphoblastic leukemia

Public title

The effect of zinc gluconate mouthwash in prevention of mucositis ,

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Age between 5 to 15 years old Acute Lymphoblastic Leukemia under the treatment of Children's Oncology Group (COG) chemotherapy protocol High dose of methotrexate No mucositis before receiving methotrexate No nausea and vomiting before starting methotrexate Platelet count above 100,000 per μ l before From the onset of methotrexate The absolute neutrophil count exceeds 1500 ml / μ l before starting methotrexate Hemoglobin above 8 g / l Before starting methotrexate, the ability to use mouthwash for 30 seconds every 8 hours

Exclusion criteria:

Presence of fever Use of systemic or topical antibiotics

Age

From **5 years** old to **15 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

We divide each client into two groups using a random table. This table is a set of numbers. Consider the numbers 1 to 30 for intervention A and the numbers 31 to 60 for control B (for both size groups larger and smaller than 4 cm). Then we touch one of the numbers and move into one of the predetermined directions and record the numbers and assign them to one of the groups. In this way, patients are divided completely randomly.

Blinding (investigator's opinion)

Double blinded

Blinding description

Each patient will be informed by the dentist prior to receiving the drug in terms of the severity and severity of the mucositis. The dentist will not be aware of the

patient who is rejected (case or control). For the patient, starting with the 24-hour infusion, methotrexate is given every 8 hours for mouthwash and at least 30 seconds for oral mouthwash. In the control group, the patient receives a standard oral mucosa (containing 100,000 units of nystatin in a cc + diphenhydramine 2.5 mg per cc + 260 cc of MG aluminum syringe). The case group in each patient uses the same oral mucosal episode in the same container containing the above plus 1mili grams in cc of zinc gluconate, The above mouthwash is prepared in coordination with the pharmacy department of the pharmacy of Bu Ali Hospital in Sari and under the supervision of the pharmacist's colleague, Dr. Sahraei. Patients are not aware of the type of mouthwash in each patient-episode The nurse in the oncology department monitors the proper use of mouthwash and, if not properly used, to be excluded from the study

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Mazandaran University of Medical Sciences

Street address

Central Headquarters of Mazandaran University of Medical Sciences, at the beginning of Valiasr Highway, Joibar Three Ways, Imam Square, Sari

City

Sari

Province

Mazandaran

Postal code

3397148157

Approval date

2020-04-04, 1399/01/16

Ethics committee reference number

IR.MAZUMS.REC.1399.048

Health conditions studied**1****Description of health condition studied**

Acute Lymphoblastic Leukemia

ICD-10 code

C91.0

ICD-10 code description

Acute lymphoblastic leukemia [ALL]

Primary outcomes

1

Description

Severity of Mucositis

Timepoint

Before receiving the drug and re-day four after the onset of methotrexate

Method of measurement

By the dentist and according to the Criteria WHO

2

Description

Periods of Mucositis

Timepoint

Before receiving the drug and re-day four after the onset of methotrexate

Method of measurement

By the dentist and according to the Criteria WHO

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Each patient is evaluated for the presence and severity of mucositis before receiving the drug by the dentist. For the patient, mouthwash which is performed every 8 hours from the start of the 24-hour infusion of methotrexate which prepared in Mazandaran School of Pharmacy and keeping the mouthwash in the mouth for at least 30 seconds. In the intervention group, each patient uses mouthwash in the same container containing the above plus 1 mg / cc zinc gluconate which has been prepared by the design consultant pharmacist in the same way. The patients studied are not aware of the type of mouthwash used in each patient-episode. In both groups, the number of nausea and vomiting and daily food intake are recorded. Patients are re-examined on the 4th day after the start of methotrexate by a partner dentist and the mucositis is registered according to the criteria of the World Health Organization.

Category

Treatment - Drugs

2

Description

Control group: Each patient will be co-supervised by the dentist prior to receiving the drug in terms of the existence and severity of mucositis. The patient is given a mouthwash at least 30 seconds after starting the 24-hour infusion of methotrexate which was prepared in Mazandaran School of Pharmacy every 8 hours for mouthwash. In both groups, the frequency of nausea and vomiting and food intakes are recorded daily. People

again on day 4 after starting methotrexate are checked out by a dentist who is a collaborator and mucositis is recorded according to the WHO criteria. If mucositis is present, again, on the 7th day, a dentist will examine the presence and severity of mucositis

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Bu Ali Sina hospital

Full name of responsible person

Mohammad Naderisorki

Street address

Bu Ali Sina Hospital, Pasdarsan Boulevard, Sari

City

Sari

Province

Mazandaran

Postal code

3397148157

Phone

+98 11 3334 3015

Email

dr.naderisorki@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mazandaran University of Medical Sciences

Full name of responsible person

Dr. Majid Saeedi

Street address

Headquarters of Mazandaran University of Medical Sciences. At the beginning of Valiasr Highway, Sari

City

Sari

Province

Mazandaran

Postal code

3397148157

Phone

+98 11 3334 4506

Email

dr.naderisorki@gmail.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Mazandaran University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact

Name of organization / entity
Mazandaran University of Medical Sciences
Full name of responsible person
Mohammad Naderisorki
Position
Assistant professor
Latest degree
Subspecialist
Other areas of specialty/work
Hematology
Street address
Bou Ali Sina Hospital, Pasdaran Boulevard, Sari
City
Sari
Province
Mazandaran
Postal code
4815838477
Phone
+98 11 3334 7837
Fax
Email
dr.naderisorki@mazums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity
Mazandaran University of Medical Sciences
Full name of responsible person
Mohammad Naderisorki
Position
Assistant Professor
Latest degree
Subspecialist
Other areas of specialty/work
Pediatrics
Street address
Bou Ali Sina Hospital, Pasdaran Boulevard, Sari
City
Sari
Province

Mazandaran
Postal code
4815838477
Phone
+98 902 604 2132
Email
dr.naderisorki@gmail.com

Person responsible for updating data

Contact

Name of organization / entity
Mazandaran University of Medical Sciences
Full name of responsible person
Mohammad Naderisorki
Position
Assistant Professor
Latest degree
Subspecialist
Other areas of specialty/work
Pediatrics
Street address
Bou Ali Sina Hospital, Pasdaran Boulevard, Sari
City
Sari
Province
Mazandaran
Postal code
4815838477
Phone
+98 902 604 2132
Email
dr.naderisorki@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available