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 methotreoxate 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

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Iran (Islamic Republic of)

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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 methotreoxate 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 µl before From the onset of methotrexate The absolute neutrophil count exceeds 1500 ml / µl 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 epizood 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
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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, mouthwashWhich 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 pharmacistin 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 mocositis 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 mucositi
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Bu Ali Sina hospital
Full name of responsible person
Mohammad Naderisorki
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Sponsors / Funding sources

1

Sponsor
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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
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

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Latest degree

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Other areas of specialty/work

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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