Clinical Trial Protocol
Iranian Registry of Clinical Trials

31 May 2026

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

Protocol summary

Study aim

The study of the effect of oral glucose in prevention of mucositis, following a high dose of methotrexate in children with acute lymphoblastic leukemia

Design

Based on the statistics advice and based on previous studies, 100 patient-episodes are studied. They are divided into two groups of 50 cases or control according to the random numbers table.

Settings and conduct

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 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 16 grams in 260 cc of glutamine is used similarly. Patients are not aware of the type of mouthwash in each patient-episode. .

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age of 5 to 10 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 admitted and treated in the blood and cancer boolea group are treated with a high dose of intravenous methotrexate (5 g / 24 hours infusion) in the Interim maintenance 1 protocol. Placed.

Main outcome variables

Sex، Age، 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: **IRCT20190202042583N2**
Registration date: **2020-09-05, 1399/06/15**
Registration timing: **retrospective**

Last update: **2020-09-05, 1399/06/15**
Update count: **0**

Registration date

2020-09-05, 1399/06/15

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 glutamine mouthwash in prevention of mucositis following the administration of high doses of methotrexate in children with acute lymphoblastic leukemia

Public title
The effect of glutamine mouthwash in prevention of mucositis

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Age of 5 to 10 years ALL under the treatment of 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 Absence of mucositis at the initial visit

Exclusion criteria:
presence of fever use of systemic or topical antibiotics

Age
From **5 years** old to **10 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size
Target sample size: **100**

Randomization (investigator's opinion)
Randomized

Randomization description
After observing the inclusion criteria, a number is assigned to each patient at each time of drug administration. Then, based on the table of random numbers, the individual numbers in the control group and even numbers are placed in the case group.

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 16 grams in 260 cc of glutamine, 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
2019-12-18, 1398/09/27

Ethics committee reference number
IR.MAZUMS.REC.1398.1183

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 cafeteria WHO

2

Description

Existence 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 cafeteria WHO

3

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 cafeteria WHO

4

Description

Frequency of nausea

Timepoint

Daily measurement

Method of measurement

Observation and clinical examination

5

Description

frequency of vomiting

Timepoint

Daily measurement

Method of measurement

Observation and clinical examination

6

Description

frequency of liquid nutrition

Timepoint

Daily measurement

Method of measurement

Observation and clinical examination

7

Description

Frequency of solids Nutrition

Timepoint

Daily measurement

Method of measurement

Observation and clinical examination

Secondary outcomes

empty

Intervention groups

1

Description

Control group: Each patient with ALL at the interim maintenance stage 1 needs to receive 5 episodes of high dose methotrexate. Each patient will be co-supervised by the dentist prior to receiving the drug in terms of the existence and severity of mucositis. The dentist from the group The patient will not be aware of it (case or control). The patient is given a mouthwash at least 30 seconds after starting the 24-hour infusion of methotrexate every 8 hours for mouthwash.The mouthwash is provided by the consultant pharmacist at the Faculty of Pharmacy.The studied mothers are not aware of the type of mouthwash in each patient-episode. The oncology nurse monitors the proper use of mouthwash and, if not used correctly, is excluded from the study. 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 mucositis.

Category

Placebo

2

Description

Intervention group: Each patient with ALL at the interim maintenance stage 1 needs to receive 5 episodes of high dose methotrexate. Each patient will be co-supervised by the dentist prior to receiving the drug in terms of the existence and severity of mucositis. The dentist from the group The patient will not be aware of it (case or control). The patient is given a mouthwash at least 30 seconds after starting the 24-hour infusion of methotrexate every 8 hours for mouthwash. The case group in each patient uses the same oral mucosal episode in the same container containing the above plus 16 grams in 260 cc of glutamine, which is provided by the consultant pharmacist at the Faculty of Pharmacy.The studied mothers are not aware of the type of mouthwash in each patient-episode. The oncology nurse monitors the proper use of mouthwash and, if not used correctly, is excluded from the study. 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 mucositis

Category

Treatment - Drugs

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,Pasdarsn Boulevard,sari

City
Sari

Province
Mazandaran

Postal code
۳۳۹۷۱-۴۸۱۵۷

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
oncology

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 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
009890266042132

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