Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Evaluation of oral N-acetylcysteine efficacy versus placebo in prevention of mucositis induced by radiotherapy and chemotherapy agents in children with malignancy A double blind randomized clinical trial

Protocol summary

Study aim
Investigating the effect of N-acetylcysteine on the prevention of mucositis caused by chemotherapy drugs

Design
Clinical trial with intervention and control group, double-blind, randomized, conducted on 80 patients. The randombetween of Excel software was used for randomization.

Settings and conduct
patients with a high risk of developing oral mucositis will be divided into two treatment and control groups based on the six random block method. Patients in the treatment group get 20 to 25 mg/kg on the first day and continued with a maintenance dose of 10 to 15 mg/kg BID for another 14 days. On day 0, 7 and 15 blood samples were taken from the patients and the amount of oxidative stress factor MDA in these samples was measured and the incidence and severity of oral mucositis will be recorded.

Participants/Inclusion and exclusion criteria
Inclusion criteria: 1-Patients who are 2-18 years old 2-Recipients of radiotherapy and anti-metabolite chemotherapy drugs 3-Patients with lansky performance scale index above 70% 4-No Cardiovascular disease Exclusion criteria: 1-Causes any severe allergic reactions to the drugs 2-Any active gastrointestinal disease 3-Cardiovascular disease

Intervention groups
Intervention group: Patients treated with N-acetylcysteine tablets (200 mg) produced by a pharmaceutical company. The intervention group started the treatment on the first day with a dose of 20-25 mg/kg and with a Maintenance dose of 10 to 15 mg/kg BID will continue for another 14 days.

Main outcome variables
Efficacy of N-acetylcysteine drug on prevention of mucositis caused by radiotherapy

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20210622051666N1**
Registration date: **2023-07-02, 1402/04/11**
Registration timing: **prospective**

Last update: **2023-07-02, 1402/04/11**
Update count: **0**

Registration date
2023-07-02, 1402/04/11

Registrant information

Name
Sepideh Dadfar

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 61 3373 8380

Email address
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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-07-23, 1402/05/01

Expected recruitment end date
2024-07-22, 1403/05/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Evaluation of oral N-acetylcysteine efficacy versus placebo in prevention of mucositis induced by radiotherapy and chemotherapy agents in children with malignancy A double blind randomized clinical trial

Public title
Evaluation of oral N-acetylcysteine efficacy versus placebo in prevention of mucositis induced by radiotherapy and chemotherapy agents in children with malignancy

Purpose
Prevention

Inclusion/Exclusion criteria

Inclusion criteria:
Patients who are 2-18 years old Recipients of radiotherapy and anti-metabolite chemotherapy drugs with a high risk of developing oral mucositis (including Doxorubicin, Methotrexate, FU Etoposide, Cytarabine and Melphalan) and other drugs listed below. Patients with lansky performance scale index above 70% No Cardiovascular disease

Exclusion criteria:
Causes any severe allergic reactions to the drug (such as skin complications, bronchospasm, bronchitis, etc.) Any active gastrointestinal disease Cardiovascular disease

Age
From **2 years** old to **18 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **80**

Randomization (investigator's opinion)
Randomized

Randomization description
In this study, the size of the blocks will be equal. Also, the blinding method will be used to prevent the disclosure of information in each block. Patients entered the study in order of referral. Patients will enter the study according to the order of referral. Patients will be completely randomly divided into two treatment and control groups based on the method of random blocks of six (the sample size of this study is 80). (the length of each block is 4) (the sample size of this study is 80). The randomization sequence will be created using the randomization command in the Excel program (RandomBetween).

Blinding (investigator's opinion)
Double blinded

Blinding description
In this study, the patients are treated with the drug packages predetermined by the study supervisor. The drug packages are totally similar in terms of shape, the patient and the plan administrator are not aware of their contents. In addition, the collection of information, assessment of patients, and completion of forms are done by the project manager and her assistant, who are not aware of the contents of the package. In the stage of data analysis, it will be done by the project manager and only the patient group (Groups 1 and 2) will be determined for data analysis. Therefore, this study is double-blind and from the stage of entering the patient to the completion of the study, data collection, and information analysis, the contents of the two drug groups are not known.

Placebo
Used

Assignment
Crossover

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Ahvaz University of Medical Sciences

Street address
Ahvaz Jundishapur University of Medical Sciences, Golestan St. , Ahvaz , Iran.

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ahvaz

Province
Khouzestan

Postal code
15794-61357

Approval date
2022-10-22, 1401/07/30

Ethics committee reference number
IR.AJUMS.REC.1401.326

Health conditions studied

1

Description of health condition studied
CHEMOTHERAPY,MUCOSITIS,RADIATION THERAPY,CANCER

ICD-10 code
K12.31

ICD-10 code description
Oral mucositis (ulcerative) due to antineoplastic therapy

Primary outcomes

1

Description
The score of positive and negative symptoms in the PANSS questionnaire

Timepoint
Prevention of mucositis caused by radiotherapy at the beginning of the study (before the start of the intervention) and 7, 15 days after the start of taking N-acetylcysteine.
Method of measurement
Questionnaire of positive and negative symptoms of oral mucositis

Secondary outcomes

1

Description
The level of the oxidative stress factor Malondialdehyde in the blood
Timepoint
Measurement of the oxidative stress factor Malondialdehyde at the beginning of the study (before the start of the intervention) and 7, 15 days after the start of taking N-acetylcysteine
Method of measurement
Measurement of Malondialdehyde oxidative stress factor in patient's blood by UV spectrophotometry.

Intervention groups

1

Description
Intervention group: Patients treated with N-acetylcysteine tablets (200 mg) produced by a pharmaceutical company. The intervention group started the treatment on the first day with a dose of 20-25 mg/kg and with a Maintenance dose of 10 to 15 mg/kg BID will continue for another 14 days.
Category
Treatment - Drugs

2

Description
Control group: patients received placebo tablets, which are similar to N-acetylcysteine tablets (in terms of shape, smell, taste, size, and color) and are made from starch powder with color approved by the pharmacy laboratory of the Faculty of Pharmacy of Ahvaz University of Medical Sciences, for 15 They receive days.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Abuzar Children's Educational and Therapeutic Hospital, Ahvaz
Full name of responsible person
Mohsen Alisamir
Street address
Pediatric Hematology Clinic, Abouzar hospital, Parastar avenue, pasdaran BLVD, Ahvaz, Khouzestan, Iran
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2

Recruitment center
Name of recruitment center
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Full name of responsible person
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Baqai hospital, Begai square, Golestan highway, khouzestan, Ahvaz, Iran
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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%D8%A7%D8%B5%D9%84%DB%8C

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Ahvaz 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

Ahvaz University of Medical Sciences

Full name of responsible person

Sepideh Dadfar

Position

student

Latest degree

A Level or less

Other areas of specialty/work

Medical Pharmacy

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Farzaneh Hematian

Position

Assistant professor

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Specialist

Other areas of specialty/work

Pharmacotherapy

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Person responsible for updating data

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Name of organization / entity

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Position

Student

Latest degree

A Level or less

Other areas of specialty/work

Medical Pharmacy

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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