

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

02 Aug 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

dadfar.sepid@gmail.com

##### 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.

##### City

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, Khouzeestan, Iran

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##### Province

Khuzestan

##### Postal code

61635931

##### Phone

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##### Fax

+98 61 3444 4711

##### Email

alisamir-m@ajums.ac.ir

### 2

#### Recruitment center

##### Name of recruitment center

Shahid Baghaei Hospital

##### Full name of responsible person

Kaveh Jaseb

##### Street address

Baqai hospital, Begai square, Golestan highway, khuzestan, Ahvaz, Iran

##### City

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6138933141

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## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Ahvaz University of Medical Sciences

##### Full name of responsible person

Mehrnoosh Zakerkish

##### Street address

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aduaum@ajums.ac.ir

##### Web page address

<https://www.ajums.ac.ir/fa-IR/Portal/1/page/%D8%B5%D9%81%D8%AD%D9%87->

%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

**Street address**

Pharmacy faculty , Ahvaz Jundishapur University of Medical Sciences, Golestan St. , Ahvaz , Iran.

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**Person responsible for scientific inquiries**

**Contact**

**Name of organization / entity**

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Farzaneh Hematian

**Position**

Assistant professor

**Latest degree**

Specialist

**Other areas of specialty/work**

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**Person responsible for updating data**

**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

**Street address**

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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