

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Comparison of the effect of chamomile and gelclair on chemotherapy-induced oral mucositis in children with cancer

#### Protocol summary

##### Study aim

The effects of chamomile and chlorine gel on oral mucositis caused by chemotherapy in children with cancer are compared.

##### Design

This study is an open label clinical trial, which is study phase 3, and block randomization method was used for randomization.

##### Settings and conduct

This study is an open label clinical trial. In which the participants were divided into two identical medicinal groups of Chamomile Tea and Clair Gel by means of block randomization. In each group, the corresponding treatment is performed. Finally, two groups are evaluated and compared in terms of severity of mucositis.

##### Participants/Inclusion and exclusion criteria

Conditions for inclusion in the study: children with cancer between 2 and 15 years of age who were admitted to the oncology department of Amirkabir Arak Hospital within 3 months; consent to participate in the study. Conditions for not entering the study: history of drug allergy; presence of chronic mucocutaneous disease

##### Intervention groups

Chamomile tea group: Patients receive chamomile tea 6 times a day (every 4 hours) for 2 weeks. Clair gel group: they receive Clear gel 4 times a day for 2 weeks.

##### Main outcome variables

The severity of mucositis

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20191104045328N12**

Registration date: **2022-08-10, 1401/05/19**

Registration timing: **prospective**

Last update: **2022-08-10, 1401/05/19**

Update count: **0**

##### Registration date

2022-08-10, 1401/05/19

##### Registrant information

###### Name

Amin Haji seyyed hoseini

###### Name of organization / entity

###### Country

Iran (Islamic Republic of)

###### Phone

+98 86 3366 7583

###### Email address

amin.medstu@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2022-08-16, 1401/05/25

##### Expected recruitment end date

2022-12-16, 1401/09/25

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Comparison of the effect of chamomile and gelclair on chemotherapy-induced oral mucositis in children with cancer

##### Public title

Comparison of the effect of chamomile and gelclair on chemotherapy-induced oral mucositis

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

**Inclusion criteria:**

Children with cancer between the ages of 2 and 15 who were referred to the oncology department of Amirkabir Arak Hospital within 3 months Consent to participate in the study

**Exclusion criteria:**

History of drugs allergy Presence of chronic mucous skin disease

**Age**

From **2 years** old to **15 years** old

**Gender**

Both

**Phase**

2-3

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **50**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Participants are assigned to two intervention and control groups, respectively, based on the randomization sequence that will be generated beforehand. This sequence is unpredictable and its arrangement is completely random. Block randomization method with 8 blocks will be used to allocate samples. Thus, using block numerical random number generation software, a randomization sequence proportional to the sample size required for the two groups will be generated. Initially, all cases in which the two letters A and B can be arranged in blocks of 8 are produced. A block is then randomly selected from the blocks and the layout pattern in that block will be used to assign participants. This block will then be placed in the main container and another block will be selected again. All this will be done with software called Sealed Envelope. With this method, concealment will also be observed. The concept of concealment is to unpredictably assign individuals to groups. In fact, the researcher will not be able to predict which group the next person will be in.

**Blinding (investigator's opinion)**

Not blinded

**Blinding description****Placebo**

Not used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

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

Ethics Committee of Qom University of Medical Sciences

**Street address**

Qom, 15 Khordad Blvd., near Social Security Insurance, Islamic Azad University of Qom, Faculty of Medicine, Research Assistant

**City**

Arak

**Province**

Markazi

**Postal code**

3714668669

**Approval date**

2022-04-19, 1401/01/30

**Ethics committee reference number**

IR.IAU.QUM.REC.1401.026

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

Oral mucositis

**ICD-10 code**

K12.3

**ICD-10 code description**

Oral mucositis (ulcerative)

**Primary outcomes****1****Description**

The severity of mucositis

**Timepoint**

1st, 7th and 14th day of treatment

**Method of measurement**

Physical examination

**Secondary outcomes**

empty

**Intervention groups****1****Description**

Intervention group: Patients receive chamomile tea 6 times a day (every 4 hours) for 2 weeks.

**Category**

Treatment - Drugs

**2****Description**

Intervention group: they receive Clear gel 4 times a day for 2 weeks.

**Category**

Treatment - Drugs

**Recruitment centers**

## 1

### Recruitment center

**Name of recruitment center**

Arak Amir Kabir Hospital

**Full name of responsible person**

Dr. Vahid Falahati

**Street address**

Vice Chancellor for Education, Amir Kabir Hospital,  
Arak, Iran

**City**

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**Province**

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**Postal code**

3819691187

**Phone**

+98 86 3222 2003

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**Email**

vahidfalahati@arakmu.ac.ir

### Sponsors / Funding sources

## 1

### Sponsor

**Name of organization / entity**

Islamic Azad University

**Full name of responsible person**

Dr. Gholamreza Najafi

**Street address**

Qom, 15 Khordad Blvd., near Social Security  
Insurance, Islamic Azad University of Qom, Faculty of  
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qom@cms.iau.ir

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Islamic Azad University

**Proportion provided by this source**

100

**Public or private sector**

Private

**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**

Iran University of Medical Sciences

**Full name of responsible person**

Dr. Elham Ramezani

**Position**

Associate professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Pediatrics

**Street address**

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Elham96261@gmail.com

### Person responsible for scientific inquiries

**Contact****Name of organization / entity**

Arak University of Medical Sciences

**Full name of responsible person**

Dr. Vahid Falahati

**Position**

Associate professor

**Latest degree**

Subspecialist

**Other areas of specialty/work**

Hematology

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## Person responsible for updating data

### Contact

**Name of organization / entity**

Ghoum University of Medical Sciences

**Full name of responsible person**

Sepideh Armanfar

**Position**

University student

**Latest degree**

A Level or less

**Other areas of specialty/work**

General Practitioner

**Street address**

No. 7555, Taraj building, Zamangir alley 2, Ahmed Abadi alley, Jomhuri street, Mustafa Khomeini town, Arak

**City**

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**Province**

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**Postal code**

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**Phone**

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**Email**

Armanfar.sepide@gmail.com

## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

**Study Protocol**

Yes - There is a plan to make this available

**Statistical Analysis Plan**

Yes - There is a plan to make this available

**Informed Consent Form**

Yes - There is a plan to make this available

**Clinical Study Report**

Yes - There is a plan to make this available

**Analytic Code**

Yes - There is a plan to make this available

**Data Dictionary**

Yes - There is a plan to make this available

**Title and more details about the data/document**

After conducting this study and analytical studies on it, only a part of the data such as information about the main outcome and patient demographic information will be published to the researchers who do the necessary correspondence with the person in charge of this study.

**When the data will become available and for how long**

Access will be from 2023/4/20 to 2026/4/20 for 3 years.

**To whom data/document is available**

University researchers

**Under which criteria data/document could be used**

Academic researchers or university professors or students who intend to use the data of this study, after obtaining permission from the relevant people mentioned, can use the information of this study in the field of metallurgical studies or other relevant review studies. In addition, if requested, they can use the information of this study for the prerequisites of their future studies and the existence of questions and ambiguities. Using the information of this study is subject to mentioning the names and logos of the responsible persons in this study.

**From where data/document is obtainable**

University researchers and university professors, after contacting the relevant professor by text message or e-mail, can request the use of data from Dr. Ramezani and then Dr. falahati, respectively. Dr. Elham Ramezani: Address: Qom, 15 Khordad Blvd., near Social Security Insurance, Islamic Azad University of Qom, Faculty of Medicine, Research Assistant. Postal Code: 3714668669 Phone: 09123519544 Email: Elham96261@gmail.com Dr. Vahid Falahati Address: Hospital Education Vice-Chancellor, Amirkabir Hospital, Arak Postal Code: 3814957558 Phone: 09133065573 Email: vahidfalahati@arakmu.ac.ir

**What processes are involved for a request to access data/document**

Letter writing should be done with professors and universities.

**Comments**