Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 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

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Islamic Azad University

Full name of responsible person
Dr. Gholamreza Najafi

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

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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
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

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Person responsible for scientific inquiries

Contact

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Associate professor

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Other areas of specialty/work
Hematology

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Person responsible for updating data

Contact

Name of organization / entity
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Full name of responsible person
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Position
University student

Latest degree
A Level or less

Other areas of specialty/work
General Practitioner

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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: 09133065573Email: 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