Clinical Trial Protocol
Iranian Registry of Clinical Trials

28 May 2026

Comparison of the effect of hydroalcoholic extract of (Achillea Wihelmsii C.Koch) and routine treatment on chemotherapy-induced nausea and vomiting and quality of life in children aged 8-18 years with cancer

Protocol summary

Study aim

Determining the effect of Achillea Wilhelmsii C.Koch hydroalcoholic extract on chemotherapy-induced nausea and vomiting and quality of life in children aged 8-18 years with cancer

Design

This study is a double blinded clinical trial in which patients will be assigned to control and intervention groups using randomized block allocation and creating different number of blocks. The number of samples in this study is 40 people.

Settings and conduct

40 children aged 8-18 years with cancer referred to Seyed al-Shohda Hospital in Isfahan (Omid) who are eligible to enter the study will be selected through convenient sampling. And after obtaining informed consent, patients will be assigned to two control and intervention groups using random block allocation. The intervention group will receive capsules containing Achillea Wilhelmsii extract for one week, and the control group will receive placebo capsules. The study is a double-blind clinical trial. The drug prescriber and the patient themselves do not know the type of drug (placebo or plant extract).

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1. Children with cancer under chemotherapy that have nausea and vomiting 2. Having the informed consent of the children under study and legal guardian 3. Normal hematological and biochemical laboratory values of blood Exclusion criteria: 1. Gastrointestinal diseases and cancers related to the gastrointestinal tract according to the discretion of the specialist physician 2. History of allergy to Achillea

Intervention groups

The intervention group is children with cancer undergoing chemotherapy who receive Achillea Wihelmsii C.Koch capsule intervention. The control group includes children with cancer undergoing chemotherapy who receive routine treatment intervention.

Main outcome variables

Nausea; Vomit; Quality of Life

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190120042436N4**
Registration date: **2022-07-09, 1401/04/18**
Registration timing: **prospective**

Last update: **2022-07-09, 1401/04/18**
Update count: **0**

Registration date

2022-07-09, 1401/04/18

Registrant information

Name

Mohsen Salari

Name of organization / entity

Country

Iran (Islamic Republic of)

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salarimo@yums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-07-22, 1401/04/31

Expected recruitment end date

2022-11-21, 1401/08/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of hydroalcoholic extract of (Achillea Wihelmsii C.Koch) and routine treatment on chemotherapy-induced nausea and vomiting and quality of life in children aged 8-18 years with cancer

Public title

The effect of Achillea Wihelmsii C.Koch on nausea and vomiting and quality of life

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age 18-8 years Having the informed consent of the children under study and legal guardian Diagnosed with cancer Having nausea and vomiting Treated with chemotherapy drugs Having at least one course of chemotherapy before the intervention Normal hematological and biochemical laboratory values of blood

Exclusion criteria:

Gastrointestinal diseases and cancers related to the gastrointestinal tract at the discretion of a fellow physician History of allergy to medicinal plants of the Achilleas family

Age

From **8 years** old to **18 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Participant
- Care provider
- Investigator

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

The block method will be used to assign people to the studied groups. Random allocation by block method is for the purpose that exactly equal number of patients enter the intervention and control groups in consecutive time intervals. Groups are formed as A, B, C. To avoid the predictable risk of assigning people to different groups, blocks with different sizes will be created. Before assigning people to one of the groups, a list of letters (A, B, C), i.e. blocks with sizes 3, 9 and 12, is formed by the reliable website https://www.sealedenvelope.com. Based on the order of coming to clinic, the children will be placed in one of the groups and this sampling will continue until the estimated sample size is reached in each group.

Blinding (investigator's opinion)

Double blinded

Blinding description

The drug (Achillea Wihelmsii C.Koch extract) and placebo are prepared in capsules of the same color by a pharmacist and are coded by the pharmacist without the prescriber and the patient being aware of the type of drug (placebo or plant extract).

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Yasuj University of Medical Sciences

Street address

shahid Jalil Street, Educational Pardis, Yasuj.

City

Yasuj

Province

Kohgilouyeh-va-Boyrahmad

Postal code

75919-94799

Approval date

2022-05-31, 1401/03/10

Ethics committee reference number

IR.YUMS.REC.1401.038

Health conditions studied

1

Description of health condition studied

nausea and vomiting

ICD-10 code

R11

ICD-10 code description

Nausea and vomiting

2

Description of health condition studied

cancer

ICD-10 code

C00-C97

ICD-10 code description

Malignant neoplasms

Primary outcomes

1

Description
nausea and vomiting
Timepoint
The number of nausea and vomiting episodes is recorded within 24 hours.
Method of measurement
Registration in Common Toxicity Criteria (CTC)

2

Description
Quality of Life
Timepoint
One week after chemotherapy
Method of measurement
Pediatric Quality of Life inventory4.0 Acute

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: In addition to receiving routine drugs to control nausea and vomiting caused by chemotherapy, the intervention group will receive two oral capsules containing 150 mg of Achillea wilhelmsii plant extract daily for one week. These capsules are made in the pharmacology department of medicinal plants of Yasouj University of Medical Sciences.
Category
Treatment - Drugs

2

Description
Control group: In addition to receiving routine drugs to control nausea and vomiting caused by chemotherapy, the control group will receive two placebo capsules daily for one week. Each placebo capsule contains 150 mg of starch. These capsules are made in the pharmacology department of medicinal plants of Yasouj University of Medical Sciences.
Category
Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Seyed Al-Shohada Hospital
Full name of responsible person
Mohsen Salari
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Yasouj University of Medical Sciences
Full name of responsible person
Dr. Hossein Mari Oryad
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Shahid Motahari Blvd., Vice Chancellor of Research, Yasuj University of Medical Sciences, Yasuj
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Email
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Web page address
http://research.yums.ac.ir/index.aspx?siteid=11&fkeyid=&siteid=11&pageid=9397
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Yasouj 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
Yasouj University of Medical Sciences

Full name of responsible person
Mohsen Salari
Position
Assistant professor
Latest degree
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Person responsible for updating data

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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