

Clinical Trial Protocol

Iranian Registry of Clinical Trials

25 Jul 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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Email address

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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.

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Yasuj

Province

Kohgiluyeh-va-Boyer-Ahmad

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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Isfahan, Motahhari Street

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Yasouj University of Medical Sciences

Full name of responsible person

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<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

Ph.D.

Other areas of specialty/work

Nursery

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Person responsible for updating data**Contact****Name of organization / entity**

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Position

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Email**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