# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

09 Nov 2026

## Studying the effectiveness of henna in preventing neuropathy caused by chemotherapy with taxane drugs in cancer patients treated with chemotherapy regimens

## Protocol summary


**Study aim**

To determine the effectiveness of henna in preventing neuropathy caused by chemotherapy with taxane drugs in patients with cancer treated with chemotherapy regimens.

**Design**

A randomized, non-blinded, controlled and parallel group clinical trial was conducted on 50 patients using a randomized permutation block design.

**Settings and conduct**

Cancer patients who are candidates for taxane therapy and who refer to Arak Khansari Hospital will be included in the study if they are eligible. They will be randomly assigned to the intervention and control groups using a randomized block design. This study is not blinded.

**Participants/Inclusion and exclusion criteria**

Inclusion criteria: Cancer patients treated with taxane-containing chemotherapy regimens receiving their first course of chemotherapy, Patients with no previous proven neuropathy. Exclusion criteria: Patients' lack of cooperation, Presence of sensitivity or allergic reaction to henna.

**Intervention groups**

Intervention group: Patients who receive Taxane every 3 weeks for 6 chemotherapy courses. After each chemotherapy course, they apply a 50-gram package of henna from Atabak Yazd Company on the palms of their hands and feet and leave it on for 8 hours. Control group: Patients who receive Taxane every 3 weeks for 6 chemotherapy courses and do not use any alternative treatment to prevent peripheral neuropathy.

**Main outcome variables**

Score of NCI-CTCAE, EORTC QLQ-CIPN20 and NPSI questionnaires, Nerve conduction velocity


## General information

**Reason for update**

**Acronym**

**IRCT registration information**

IRCT registration number: **IRCT20250607066102N1**
Registration date: **2025-07-07, 1404/04/16**
Registration timing: **registered_while_recruiting**

Last update: **2025-07-07, 1404/04/16**
Update count: **0**

**Registration date**

2025-07-07, 1404/04/16

**Registrant information**


**Name**

Sahar Rahzani

**Name of organization / entity**

**Country**

Iran (Islamic Republic of)

**Phone**

+98 86 3328 7413

**Email address**

saharrahzani79@gmail.com


**Recruitment status**

**Recruitment complete**

**Funding source**

**Expected recruitment start date**

2025-06-12, 1404/03/22

**Expected recruitment end date**

2026-06-12, 1405/03/22

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**
Studying the effectiveness of henna in preventing neuropathy caused by chemotherapy with taxane drugs in cancer patients treated with chemotherapy regimens

**Public title**
Studying the effect of henna on preventing chemotherapy-induced neuropathy

**Purpose**
Prevention

**Inclusion/Exclusion criteria**

**Inclusion criteria:**
All patients with cancer who receive taxane chemotherapy drugs. All patients receiving taxanes who are receiving their first course of chemotherapy. Patients should not have previous proven neuropathy. Patients should not have proven diabetes. Patients should not have neurological damage such as Parkinson's, stroke, seizures, etc. They should not have swelling in their hands or feet. Do not have open wounds on your hands or feet.

**Exclusion criteria:**
Having an allergy or allergic reaction to henna Lack of cooperation from patients

**Age**
From **18 years** old

**Gender**
Both

**Phase**
3

**Groups that have been masked**
*No information*

**Sample size**
Target sample size: **50**

**Randomization (investigator's opinion)**
Randomized

**Randomization description**
In this study, the random permutation block method will be used for randomization. For this purpose, a block of 6 will be used. In each block, three cards will be written with the letter I (Intervention) and three cards with the letter P (Placebo). To hide the cards, they will be placed in an envelope and turned over several times so that their order is not clear. As each participant enters, a card will be selected for him and the selected card will be set aside. This will be done for the next five patients until 6 people are identified. Then, randomization will be done in the same way for the other groups of 6 people to achieve the desired sample size. Some of the selected random blocks of 6 are as follows: PIPIIP, PPIPII, IPPIIP, PIPIPI, IPPIIP, IPIIPP, PIIIPP, IPPIIP, PIIPPI, PPIPII, LPLLPP, LLPLPP, IPPIIP (For example, the random assignment in the 6-patient block PIPIIP is as follows: the first patient is randomly assigned to treatment P, the second patient is randomly assigned to treatment I, the third patient is randomly assigned to treatment P, the fourth patient is randomly assigned to treatment I, the fifth patient is randomly assigned to treatment I, and the sixth patient is randomly assigned to treatment P.)

**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 Arak University of Medical Sciences

**Street address**
University of Medical Sciences, Basij Square, Sardasht neighborhood, arak

**City**
Arak

**Province**
Markazi

**Postal code**
3848176341

**Approval date**
2025-05-18, 1404/02/28

**Ethics committee reference number**
IR.ARAKMU.REC.1404.072

## Health conditions studied

### 1

**Description of health condition studied**
Chemotherapy-induced peripheral neuropathy

**ICD-10 code**
G13.0

**ICD-10 code description**
Paraneoplastic neuromyopathy and neuropathy

## Primary outcomes

### 1

**Description**
Chemotherapy-induced peripheral neuropathy score of European organization for research and treatment of cancer Quality of Live questionnaire Chemotherapy-Induced Peripheral Neuropathy (EORTC QLQ-CIPN20) questionnaire

**Timepoint**
3 weeks after intervention

**Method of measurement**
EORTC QLQ-CIPN20 questionnaire

### 2

**Description**
Chemotherapy-induced peripheral neuropathy score

from the Neuropathic Pain Symptom Inventory (NPSI) questionnaire

**Timepoint**
3 weeks after intervention

**Method of measurement**
NPSI questionnaire

**3**

**Description**
Chemotherapy-induced peripheral neuropathy score on the National Cancer Institute Common Terminology Criteria for Adverse Events (NCI-CTCAE) questionnaire

**Timepoint**
3 weeks after intervention

**Method of measurement**
NCI-CTCAE questionnaire

**4**

**Description**
Nerve conduction velocity (NCV)

**Timepoint**
Before the intervention and 3 weeks after the last intervention

**Method of measurement**
NCV device

## Secondary outcomes

empty

## Intervention groups

**1**

**Description**
Intervention group: Henna purchased from Atabak Company, Yazd, Iran, is made into 50-gram packets and given to patients, which is mixed with lukewarm water and applied to their hands and feet for 8 hours after each chemotherapy course, which is done every 3 weeks, and 6 chemotherapy courses are done. (Henna is used once every 3 weeks.)

**Category**
Prevention

**2**

**Description**
Control group: Do not receive any intervention to reduce chemotherapy-induced peripheral neuropathy.

**Category**
N/A

## Recruitment centers

**1**

**Recruitment center**

**Name of recruitment center**
Khansari Hospital

**Full name of responsible person**
Sahar rahzani

**Street address**
Ayatollah Khansari Hospital, End of Daneshgah Street

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## Sponsors / Funding sources

**1**

**Sponsor**

**Name of organization / entity**
Arak University of Medical Sciences

**Full name of responsible person**
Behzad Khansari Nejad

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University of Medical Sciences, Basij Square, Sardasht neighborhood, Arak

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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**
Arak 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**
Arak University of Medical Sciences

**Full name of responsible person**
Sahar Rahzani

**Position**
General medicine student
**Latest degree**
A Level or less
**Other areas of specialty/work**
General Practitioner
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## Person responsible for scientific inquiries

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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