

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Evaluation of using scalp cooling caps in prevention of chemotherapy-induced alopecia

#### Protocol summary

##### Study aim

the aim if this study is evaluating efficacy of scalp cooling cap in prevention of alopecia secondary to cancer chemotherapy .

##### Design

The current study is a clinical trail including 60 patients under treatment with one of special chemotherapy regimes which have well known total alopecia.

##### Settings and conduct

in one arm 30 patients use cooling cap from 30 minute before to 2 hours after every course of chemotherapy . In another arm 30 patients undergo the same chemotherapy regimens without using cooling cap

##### Participants/Inclusion and exclusion criteria

Include Criteria: Consent for using the cap and filling on the questionnaire; using chemotherapy regimens resulting in total alopecia in patient with Breast cancer, gonadal malignancies and soft tissue sarcomas; performance higher than 70%; age between 18 to 75 years. Excluding Criteria: melanoma; blood malignancies; liver or kidney dysfunction; migraine ; history of cryoglobulinemia; systemic lupus erythematosus ; no consent for using the caps.

##### Intervention groups

using scalp cooling cap in patient with Breast cancer, gonadal malignancies and soft tissue sarcoma with chemotherapy regimens resulting in total alopecia.

##### Main outcome variables

Alopecia

#### General information

##### Reason for update

##### Acronym

Mashhad Scalp Cooling Caps

##### IRCT registration information

IRCT registration number: **IRCT20141102019783N4**

Registration date: **2019-01-13, 1397/10/23**

Registration timing: **registered\_while\_recruiting**

Last update: **2019-01-13, 1397/10/23**

Update count: **0**

##### Registration date

2019-01-13, 1397/10/23

##### Registrant information

###### Name

Mitra Fazl Ersi

###### Name of organization / entity

Mashhad University Of Medical Science

###### Country

Iran (Islamic Republic of)

###### Phone

+98 51 3846 1516

###### Email address

fazlm1@mums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Mashhad University of Medical Sciences

##### Expected recruitment start date

2015-03-21, 1394/01/01

##### Expected recruitment end date

2019-03-21, 1398/01/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Evaluation of using scalp cooling caps in prevention of chemotherapy-induced alopecia

##### Public title

Efficacy of using scalp cooling caps in prevention of chemotherapy-induced alopecia

##### Purpose

Supportive

## Inclusion/Exclusion criteria

### Inclusion criteria:

consent for using the cap and filling on the questionnaire using chemotherapy regimens resulting in total alopecia including: 1. Doxorubicin plus cyclophosphamide followed by one of the Taxane drugs (in one, two or three-week regimens) 2. BEP regimen in gonadal malignancy 3. FEC (5Fu-Epirubicin -cyclophosphamide) regimen 4. VAC (vincristin-Doxorubicin -cyclophosphamide) regimen in sarcomas performance higher than 70% age between 18 to 75 years

### Exclusion criteria:

Melanoma Blood malignancies Liver or kidney dysfunction Migraine History of cryoglobulinemia Systemic lupus erythematosus No consent for using the caps

### Age

From **18 years** old to **75 years** old

### Gender

Both

### Phase

3

### Groups that have been masked

*No information*

### Sample size

Target sample size: **60**

### Randomization (investigator's opinion)

N/A

### Randomization description

### 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

Regional Ethics Committee of Mashhad University of Medical Sciences

##### Street address

Goreishi Building, Daneshgah St.

##### City

Mashhad

##### Province

Razavi Khorasan

##### Postal code

345 91357

#### Approval date

2015-12-09, 1394/09/18

#### Ethics committee reference number

IR.MUMS.fm.REC.1394.415

## Health conditions studied

### 1

#### Description of health condition studied

Breast malignancy

#### ICD-10 code

CD50

#### ICD-10 code description

Malignant neoplasm of breast

## Primary outcomes

### 1

#### Description

alopecia

#### Timepoint

prior to each chemotherapy cycle

#### Method of measurement

visual inspection and questionnaire based on WHO alopecia grading

## Secondary outcomes

### 1

#### Description

headache

#### Timepoint

following every cycle of chemotherapy

#### Method of measurement

questionnaire

## Intervention groups

### 1

#### Description

Using Scalp Cooling Cap 30 minutes before, during and up to 2.5 hours after chemotherapy with "Adriamycin and Cyclophosphamide" in breast cancer.

#### Category

Other

### 2

#### Description

Using Scalp Cooling Cap 30 minutes before, during and up to 1.5 hours after chemotherapy with "Paclitaxel 175 mg/m<sup>2</sup>" in breast cancer.

#### Category

Treatment - Drugs

### 3

#### Description

Using Scalp Cooling Cap 30 minutes before, during and up to 1 hour after chemotherapy with "Paclitaxel 80 mg/m<sup>2</sup>" in breast cancer

#### Category

Treatment - Drugs

## 4

### **Description**

Using Scalp Cooling Cap 30 minutes before, during and up to 2 hours after chemotherapy with "Bleomycin - Etoposide - Cisplatin" in gonadal malignancy.

### **Category**

Treatment - Drugs

## 5

### **Description**

Using Scalp Cooling Cap 30 minutes before, during and up to 2 hours after chemotherapy with "Epirubicin - Cyclophosphamide - Fluorouracil (5Fu)" in breast cancer.

### **Category**

Treatment - Drugs

## 6

### **Description**

Using Scalp Cooling Cap 30 minutes before, during and up to 2 hours after chemotherapy with "Vincristine - Adriamycin - Cyclophosphamide" in soft tissue sarcoma.

### **Category**

Treatment - Drugs

## 7

### **Description**

Chemotherapy with "Adriamycin and Cyclophosphamide" in breast cancer without using scalp cooling cap.

### **Category**

Treatment - Drugs

## 8

### **Description**

Chemotherapy with "Paclitaxel 175 mg/m<sup>2</sup>" in breast cancer without using scalp cooling cap.

### **Category**

Treatment - Drugs

## 9

### **Description**

Chemotherapy with "Paclitaxel 80 mg/m<sup>2</sup>" in breast cancer without using scalp cooling cap.

### **Category**

Treatment - Drugs

## 10

### **Description**

Chemotherapy with "Bleomycin - Etoposide - Cisplatin" in gonadal malignancy without using scalp cooling cap.

### **Category**

Treatment - Drugs

## 11

### **Description**

Chemotherapy with "Epirubicin - Cyclophosphamide - Fluorouracil (5Fu)" in breast cancer without using scalp

cooling cap

### **Category**

Treatment - Drugs

## 12

### **Description**

Chemotherapy with "Vincristine - Adriamycin - Cyclophosphamide" in soft tissue sarcoma without using scalp cooling cap.

### **Category**

Treatment - Drugs

## **Recruitment centers**

### 1

#### **Recruitment center**

##### **Name of recruitment center**

Omid hospital

##### **Full name of responsible person**

Mitra Fazl Ersi

##### **Street address**

Alandasht Sq., Koohsangi St.

##### **City**

Mashhad

##### **Province**

Razavi Khorasan

##### **Postal code**

9176613775

##### **Phone**

+98 51 3846 1518

##### **Email**

mitrafazlersi@gmail.com

### 2

#### **Recruitment center**

##### **Name of recruitment center**

Emam Reza hospital

##### **Full name of responsible person**

Mitra Fazl Ersi

##### **Street address**

Emam Reza Sq.

##### **City**

Mashhad

##### **Province**

Razavi Khorasan

##### **Postal code**

9137913316

##### **Phone**

+98 51 3854 3031

##### **Email**

mitrafazlersi@gmail.com

### 3

#### **Recruitment center**

##### **Name of recruitment center**

Hasheminejad hospital

##### **Full name of responsible person**

Mitra Fazl Ersi

##### **Street address**

Abureyhan Street, Mofatteh Ave.

**City**

Mashhad

**Province**

Razavi Khorasan

**Postal code**

9155788869

**Phone**

+98 51 3273 7011

**Email**

mitrafazlersi@gmail.com

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**

Vice chancellor for research, Mashhad University of Medical Sciences

**Full name of responsible person**

Marjan Ardakanian

**Street address**

Daneshgah Street, Ghoreishi Building

**City**

Mashhad

**Province**

Razavi Khorasan

**Postal code**

345 - 91357

**Phone**

+98 51 3843 3363

**Email**

vcresearch@mums.ac.ir

**Grant name**

**Grant code / Reference number**

**Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Vice chancellor for research, Mashhad 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**

Mashhad University of Medical Sciences

**Full name of responsible person**

Mitra Fazl Ersi

**Position**

Radiation Oncologist

**Latest degree**

Specialist

**Other areas of specialty/work**

Radiotherapy

**Street address**

Omid hospital, Alandasht Sq., Koohsangi St.

**City**

Mashhad

**Province**

Razavi Khorasan

**Postal code**

9176613775

**Phone**

+98 51 3846 1518

**Fax**

**Email**

mitrafazlersi@gmail.com

**Web page address**

## Person responsible for scientific inquiries

#### Contact

**Name of organization / entity**

Mashhad University of Medical Sciences

**Full name of responsible person**

Roham Salek

**Position**

Professor (in Radiotherapy & Oncology)

**Latest degree**

Specialist

**Other areas of specialty/work**

Radiotherapy

**Street address**

Omid hospital, Alandasht Sq., Koohsangi St.

**City**

Mashhad

**Province**

Razavi Khorasan

**Postal code**

9176613775

**Phone**

+98 51 3846 1518

**Fax**

**Email**

salekr@mums.ac.ir

**Web page address**

## Person responsible for updating data

#### Contact

**Name of organization / entity**

Mashhad University of Medical Sciences

**Full name of responsible person**

Mitra Fazl Ersi

**Position**

Radiation Oncologist

**Latest degree**

Specialist

**Other areas of specialty/work**

Radiotherapy

**Street address**

Omid hospital, Alandasht Sq., Koohsangi St.

**City**

Mashhad

**Province**

Razavi Khorasan

**Postal code**

9176613775

**Phone**

+98 51 3846 1518

**Fax****Email**

mitrafazlersi@gmail.com

**Web page address****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