

Clinical Trial Protocol

Iranian Registry of Clinical Trials

05 Jun 2026

Comparison of the effect of 5% minoxidil and topical epinephrine on the prevention of chemotherapy-induced hair loss in patients with breast cancer compared to the control group (placebo recipients)

Protocol summary

Study aim

Determination of the effect of 5% minoxidil and topical epinephrine solution on the interval between chemotherapy-induced hair loss hair regrowth, duration of hair loss, and prevention of hair loss Comparison of the efficacy of 5% minoxidil, topical epinephrine, and placebo on the interval to chemotherapy-induced hair loss

Design

Participants will randomly be divided into three groups of 21 patients using a statistical software. All three groups will be matched for age, sex, and other demographic characteristics. This phase-3 study is a parallel group, double blind, randomized controlled trial.

Settings and conduct

Eligible patients will receive the drugs 1 hour before, during, and 1 month after chemotherapy. They will be examined every 2-3 weeks and trichoscopy will be performed using the FotoFinder at the beginning, the second or third time, the last time, and 1 month after chemotherapy.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients with breast cancer referred to Shohadaye Tajrish Hospital for chemotherapy including adriamycin, cyclophosphamide, and taxol in 2020-2021, informed consent to participate in the study. Exclusion criteria: Presence of metastasis or inflammatory scalp disease, other causes of hair loss such as telogen effluvium, lichen planopilaris, discoid lupus erythematosus, and pregnant or lactating women

Intervention groups

Participants will randomly be divided into three groups of 21 patients using a statistical software. One group will receive 5% minoxidil, the second group will receive 5 micro gram topical epinephrine, and the third group will receive placebo (1 ml alcohol) twice a day.

Main outcome variables

age, gender, duration of chemotherapy, doses of drugs, efficacy of drugs, severity of drug complications, marital status, education, occupation, presence of metastasis

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200205046380N1**

Registration date: **2020-03-16, 1398/12/26**

Registration timing: **registered_while_recruiting**

Last update: **2020-03-16, 1398/12/26**

Update count: **0**

Registration date

2020-03-16, 1398/12/26

Registrant information

Name

khatere zahedi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8804 5103

Email address

khaterezahedi@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-12-22, 1398/10/01

Expected recruitment end date

2021-03-10, 1399/12/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of 5% minoxidil and topical epinephrine on the prevention of chemotherapy-induced hair loss in patients with breast cancer compared to the control group (placebo recipients)

Public title

Comparison of the effect of 5% minoxidil and topical epinephrine on the prevention of chemotherapy-induced hair loss in patients with breast cancer compared to the control group (placebo recipients) in 1398-1399

Purpose

Prevention

Inclusion/Exclusion criteria**Inclusion criteria:**

Patients with breast cancer referred to Shohadaye Tajrish Hospital for chemotherapy including adriamycin, cyclophosphamide, and taxol in 2020-2021 Informed consent to participate in the study

Exclusion criteria:

Presence of metastasis Presence of inflammatory scalp diseases Patients with other causes of hair loss including telogen effluvium, lichen planopilaris, and discoid lupus erythematosus Pregnant or lactating women

Age

No age limit

Gender

Female

Phase

3

Groups that have been masked

- Participant
- Investigator
- Data analyser

Sample size

Target sample size: **63**

More than 1 sample in each individual

Number of samples in each individual: **21**

63 patients will randomly be divided into 3 groups of 21 individuals eligible to enter the study

Randomization (investigator's opinion)

Randomized

Randomization description

Patients will be divided into three blocks (A, B, and C) by block randomization. Each block will contain 21 patients. A random allocation software will determine which patients go into which block. Then the three interventions including 5% minoxidil, topical epinephrine, and placebo will randomly be assigned to blocks A, B, or C.

Blinding (investigator's opinion)

Double blinded

Blinding description

In this study, the principle investigator, all the participants, and the data analyzer will be blinded.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee of Shahid Beheshti University of Medical Sciences

Street address

Bldg No.2 SBUMS, Arabi Ave, Daneshjoo Blvd, Velenjak, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1983963113

Approval date

2019-12-17, 1398/09/26

Ethics committee reference number

IR.SBMU.SRC.REC.1398023

Health conditions studied**1****Description of health condition studied**

Chemotherapy-induced hair loss

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

The evaluation of anagen hair count in trichoscopic findings of patients

Timepoint

The first time, the second or third time, the last time and one month after chemotherapy

Method of measurement

FotoFinder device

Secondary outcomes

empty

Intervention groups**1****Description**

The first intervention group will receive 1 ml of 5% minoxidil prepared by Shahid Beheshti Pharmacology Group twice a day.

Category

Prevention

2**Description**

The second intervention group will receive 1 ml of topical epinephrine solution prepared by Shahid Beheshti Pharmacology Group twice a day.

Category

Prevention

3**Description**

The third intervention group will receive 1 ml of alcohol (placebo) prepared by Shahid Beheshti Pharmacology Group twice a day.

Category

Prevention

Recruitment centers**1****Recruitment center****Name of recruitment center**

Shohadaye Tajrish Hospital

Full name of responsible person

Dr. Mohammad Mehdi Forouzanfar

Street address

Shohadaye Tajrish Hospital, Tajrish Square, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1989934148

Phone

+98 21 25719

Fax

+98 21 2271 9014

Email

pr_shohada@sbmu.ac.ir

Web page address**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Dr. Gholmali Tabarsa

Street address

SBUMS, Arabi Ave, Daneshjoo Blvd, Velenjak, Tehran, Iran

City

tehran

Province

Tehran

Postal code

1983969411

Phone

+98 21 29901

Fax

+98 21 2243 1919

Email

pr.office@mail.sbu.ac.ir

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Shahid Beheshti 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**

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Khetere Zahedi

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Dermatology

Street address

No. 3, Sahand Tower, Vanak Park Complex, Alikhani Blvd., South Shiraz Ave., Kordestan St., Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1436943415

Phone

002188045103

Email

khaterezahedi4819@gmail.com

Person responsible for scientific inquiries**Contact**

Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Khatere Zahedi
Position
Resident
Latest degree
Medical doctor
Other areas of specialty/work
Dermatology
Street address
No. 3, Sahand Tower, Vanak Park Complex, Alikhani Blvd., South Shiraz Ave., Kordestan St., Tehran, Iran
City
Tehran
Province
Tehran
Postal code
14369-43415
Phone
+98 21 8804 5103
Email
khaterezahedi@sbmu.ac.ir

Person responsible for updating data

Contact
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Khatere Zahedi
Position
Resident
Latest degree
Medical doctor
Other areas of specialty/work
Dermatology
Street address
No. 3, Sahand Tower, Vanak Park Complex, Alikhani Blvd., South Shiraz Ave., Kordestan St., Tehran, Iran
City
Tehran
Province
Tehran
Postal code
14369-43415

Phone
+98 21 8804 5103
Email
khaterezahedi@sbmu.ac.ir

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

Information about the timing of diagnosis of breast cancer, the stage of the disease, the time of first episode of chemotherapy, the intervals of chemotherapy, the type of medication used by the patient, the side effects of the drug, and the analysis of trichoscopic data (with FotoFinder device).

When the data will become available and for how long

The data can be accessed after the publication of the results

To whom data/document is available

People working in academic and scientific institutions

Under which criteria data/document could be used

Data can only be used to improve individuals' disease condition.

From where data/document is obtainable

Dr. Khatere Zahedi 00989132154819
khaterezahedi4819@gmail.com

What processes are involved for a request to access data/document

Request via email with complete identification data of the individual, the institution he/she works in, thorough explanation of the reason of the request. Data can be accessed after investigation of the responsible agent.

Comments