Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 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 randmoization. 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

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Dr. Gholmali Tabarsa

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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

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

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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