

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

06 Jul 2026

### Evaluation the transplatation of tissue-engineered skin containing hair follicles in androgenetic alopecia; a phase 1 clinical trial

#### Protocol summary

##### Study aim

1- Assessment of probable local or systemic side effects after tissue-engineered skin containing hair follicles engraftment 2. Determine the number and thickness of formed hairs

##### Design

One group, uncontrolled, phase I clinical trial among 5 patients and 6 months follow up

##### Settings and conduct

Participants suffering from male pattern hair loss referring to the Skin and Stem Cells Center, will receive autologous tissue engineered hair follicle onto the target area and the area will be bandaged. Participants will be screened for safety of transplantation, and thickness, density and number of formed hairs using Trichograms every four weeks for 6 months

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: age more than 25, male, Hamilton scaling male pattern hair loss more than 3. Exclusion criteria: History of malignancy, Known chronic disease, Systemic or local active infection, History of cell therapy or hair transplantation, Viral infections (HBV, HIV, HCV)

##### Intervention groups

Intervention group: Participants underwent tissue engineered skin containing hair follicles

##### Main outcome variables

Safety; thickness, density and number of formed hairs

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20080901001159N32**

Registration date: **2021-03-09, 1399/12/19**

Registration timing: **prospective**

Last update: **2021-03-09, 1399/12/19**

Update count: **0**

##### Registration date

2021-03-09, 1399/12/19

##### Registrant information

###### Name

Mohamad Ali Nilforoushzadeh

###### Name of organization / entity

Skin and Stem Cell Research Center, Tehran  
University of Medical sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 21 2220 5158

###### Email address

sdllrc@mui.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2021-09-23, 1400/07/01

##### Expected recruitment end date

2022-03-16, 1400/12/25

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Evaluation the transplatation of tissue-engineered skin containing hair follicles in androgenetic alopecia; a phase 1 clinical trial

##### Public title

Evaluation of tissue-engineered hair follicles in hair loss

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

**Inclusion criteria:**

Hamilton scaling male pattern hair loss more than 3

**Exclusion criteria:**

History of malignancy Known chronic disease Systemic or local active infection History of cell therapy or hair transplantation Viral infections (HBV,HIV , HCV) History of allergies and sensitivities Patients with contact dermatitis, psoriasis, itching or dry skin Mood disorders, depression, or neuropathy Anti coagulative drugs Hypo/hyperthyroidism

**Age**

From **25 years** old

**Gender**

Male

**Phase**

1

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **5**

**Randomization (investigator's opinion)**

N/A

**Randomization description****Blinding (investigator's opinion)**

Not blinded

**Blinding description****Placebo**

Not used

**Assignment**

Single

**Other design features****Secondary Ids**

empty

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

Ethics committee of Tehran University of Medical Sciences

**Street address**

Deputy for research and Technology, Central building, Tehran University of Medical Sciences, Qods street, Keshavarz boulevard

**City**

Tehran

**Province**

Tehran

**Postal code**

1416613675

**Approval date**

2020-12-02, 1399/09/12

**Ethics committee reference number**

IR.TUMS.MEDICINE.REC.1399.841

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

Androgenetic alopecia

**ICD-10 code**

L64

**ICD-10 code description**

Androgenic alopecia

**Primary outcomes****1****Description**

Safety

**Timepoint**

Intervention start date up to 6 months

**Method of measurement**

Medical history and physical examination

**Secondary outcomes****1****Description**

Number of formed hairs

**Timepoint**

Before intervention, every 4 weeks up to 6 months

**Method of measurement**

Trichogram

**2****Description**

Thickness of formed hairs

**Timepoint**

Before intervention, every 4 weeks up to 6 months

**Method of measurement**

Trichogram

**3****Description**

Density of formed hairs

**Timepoint**

Before intervention, every 4 weeks up to 6 months

**Method of measurement**

Trichogram

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

Intervention group: Tissue engineered skin in 3 cm diameter containing 100 hair follicles, single session engraftment

**Category**

Treatment - Other

## Recruitment centers

1

### Recruitment center

**Name of recruitment center**

Skin and Stem cell Research Center

**Full name of responsible person**

Mohammad Ali Nilforoushzadeh

**Street address**

Maryam alley, Pasha Zahari street, South Kamranieh

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nilforoushzadeh@mui.ac.ir

**Web page address**

<http://skinstemcell.ir/>

## Sponsors / Funding sources

1

### Sponsor

**Name of organization / entity**

Skin and Stem cell Research Center of Tehran  
University of Medical Sciences

**Full name of responsible person**

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tmarkaz@yahoo.com

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

Yes

**Title of funding source**

Skin and Stem cell Research Center of Tehran 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**

Skin and Stem Cells Research Center of Tehran  
University of Medical Sciences

**Full name of responsible person**

Amir Bajouri

**Position**

PhD student

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Cell science and application

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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Skin and Stem Cell Research Center, Tehran  
University of Medical sciences

**Full name of responsible person**

Mohamad Ali Nilforoushzadeh

**Position**

Professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Dermatology

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## Person responsible for updating data

### Contact

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**Full name of responsible person**

Amir Bajouri

**Position**

PhD student

**Latest degree**

Medical doctor

**Other areas of specialty/work**

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## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

Yes - There is 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**

Yes - There is 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**

Not applicable

**Data Dictionary**

Undecided - It is not yet known if there will be a plan to make this available

**Title and more details about the data/document**

Participants' data will be shared after unidentifiable of the patients

**When the data will become available and for how long**

6 months after paper publication

**To whom data/document is available**

Academic researchers

**Under which criteria data/document could be used**

In term of analysis the data related to participants

**From where data/document is obtainable**

bajouri.md@gmail.com

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

The request will be assessed by research committee of Skin and Stem cells research center which will be taken around 1-2 months

**Comments**