

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Comparison of the Outcome of Partial Thickness Skin Graft Harvesting from Scalp with the Calf for Scalp Skin Defects

Protocol summary

Study aim

Comparison of the results of partial thickness skin graft of the scalp with partial thickness skin graft of the leg for the treatment of scalp skin defects

Design

A randomized controlled study, with 40 patients between January 2018 and March 2019 and followed for three months

Settings and conduct

Study place: plastic surgery ward of Besat Hospital in Hamedan. The partial thickness skin graft from healthy scalp areas adjacent to the scalp defect. The middle thickness (inch 0.04) skin tissue is prepared with D80 or D42 electric dermatome or manual dermatome. The donor area is covered by a layer of gas, and then a layer of dry gas. The skin graft is covered in the recipient region follows the principles of plastic surgery with tie-over dressing. Some complications and outcomes such as pain, graft take, total epithelialization time, patient satisfaction in terms of cosmetic and scar removal induced by the graft in healthy and distant areas of the limbs, folliculitis, scab formation, and alopecia are evaluating in determined dates after the surgery.

Participants/Inclusion and exclusion criteria

Inclusion criteria: all patients of any age and gender with scalp defect requiring the skin graft repair primarily for existing defect or secondary to repair the defect resulting from rotation of flap in the scalp. Exclusion criteria: patient dissatisfaction, scarring or skin diseases such as eczema, folliculitis, tumoral or precancerous lesions, such as keratosis, scarring scalps due to severe scalp burns or atrophy, or radiation

Intervention groups

Intervention group: patients with scalp skin defects with various etiologies that scalp skin graft is used for them. Control group: twenty patients with scalp defects treated with routine and commonly used skin grafts (leg skin graft).

Main outcome variables

Graft take; patient pain after grafting; patient satisfaction

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170114031928N2**

Registration date: **2018-08-16, 1397/05/25**

Registration timing: **registered_while_recruiting**

Last update: **2018-08-16, 1397/05/25**

Update count: **0**

Registration date

2018-08-16, 1397/05/25

Registrant information

Name

Mehrdad Taghipour

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 81 3262 4331

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-12-22, 1396/10/01

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

Comparison of the Outcome of Partial Thickness Skin Graft Harvesting from Scalp with the Calf for Scalp Skin Defects

Public title

Evaluating the effects of Partial Thickness Skin Graft Harvesting from Scalp for Scalp Skin Defects

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

All patients of any age and gender with scalp defect requiring repair of the skin graft primarily for the present defect or secondary to the defect in order to repair the defect result from flap rotation in the scalp.

Exclusion criteria:

Patient dissatisfaction, scarring or skin disease that prevents skin graft from the scalp, such as eczema, folliculitis, tumor or pre-cancerous lesions such as keratosis, scalp scar due to severe scalp burn or severe atrophy, or radiation

Age

No age limit

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: 40

Randomization (investigator's opinion)

Randomized

Randomization description

Patients of all ages and sexes were randomly assigned into two groups of 20 patients and 20 patients receiving routine treatment.

Blinding (investigator's opinion)

Not blinded

Blinding description**Placebo**

Not used

Assignment

Other

Other design features**Secondary Ids**

empty

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

Ethics committee of Hamadan University of Medical Sciences

Street address

Shahid Beheshti Blvd, Besat Hospital

City

Hamedan

Province

Hamadan

Postal code

48138

Approval date

2018-06-30, 1397/04/09

Ethics committee reference number

IR.UMSHA.REC.1397.224

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

Scalp skin defect

ICD-10 code

T20

ICD-10 code description

Burn and corrosion of head, face, and neck

2**Description of health condition studied**

Scalp skin defect

ICD-10 code

C43.4

ICD-10 code description

Malignant melanoma of scalp and neck

3**Description of health condition studied**

Scalp skin defect

ICD-10 code

D23.4

ICD-10 code description

Other benign neoplasm of skin of scalp and neck

4**Description of health condition studied**

Scalp skin defect

ICD-10 code

S08

ICD-10 code description

Avulsion and traumatic amputation of part of head

5**Description of health condition studied**

Scalp skin defect

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

1

Description

Pain score in VAS index

Timepoint

measuring of the pain based on VAS score during the days 5, 16,35 and 90

Method of measurement

VAS score checklist

2

Description

Graft take based on Likert index

Timepoint

graft take during the days 5,16,35 and 90

Method of measurement

Likert score checklist

Secondary outcomes

1

Description

Patient Satisfaction

Timepoint

At the end of the study

Method of measurement

Likert index

Intervention groups

1

Description

Intervention group: Partial thickness skin graft from healthy areas of the adjacent scalp and scalp defect/ electric dermatome D80 or D42 or manual dermatome for the preparation of middle-thickness skin grafts (0.04 inch) / Marking the skin of scalp in Temporal, parietal or occipital areas with methylene blue / the designed area swells with infusion of some normal saline solution/defects up to 50% of the scalp can be reconstituted with 50% of the rest of the skull's healthy skin. The donor area is covered by a gas and jelly layer followed by a dry gaseous layer/ the graft in the receptor is covered in accordance with the principles of plastic surgery with "tie-over dressing" and then the entire scalp including the receiver and donor area is enclosed with Sergi Fix.

Category

Treatment - Surgery

2

Description

Control group: Twenty-one patients with scalp defects that are treated with the routine and commonly used skin graft (leg skin graft) are selected as a control group.

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Besat hospital

Full name of responsible person

Mehrdad Taghipour

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Hamadan, Shahid Beheshti Boulevard, Besat hospital

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Saeed Bashirian

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Hamadan, Shariati Ave, Shahid fahmideh blvd, vice-chancellor for research and technology

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s.bashirian@yahoo.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Hamedan 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

Hamedan University of Medical Sciences

Full name of responsible person

Mehrdad Taghipour

Position

Resident of General Surgery

Latest degree

Medical doctor

Other areas of specialty/work

General Surgery

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Person responsible for scientific inquiries

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Full name of responsible person

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Associated professor

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Subspecialist

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Person responsible for updating data

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Full name of responsible person

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Position

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Latest degree

Medical doctor

Other areas of specialty/work

General Surgery

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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

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

All results from the analysis of the preliminary data of the study and the resulting article will be shared.

When the data will become available and for how long

Access to the data will be possible immediately after the final paper is printed.

To whom data/document is available

All authors, researchers, and clinical experts will have access to the data of this study.

Under which criteria data/document could be used

A broad analysis of data of this study will be welcomed along with data from other studies for writing meta-analytic review articles.

From where data/document is obtainable

For more information, please contact Dr. Mehrdad Taghipour on 09128407085. All correspondence with e-mail: m.taghipour@edu.umsha.ac.ir will be accepted.

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

After making a phone call and submitting an application in the mail, the final reply will be sent at least one month.

Comments