

Clinical Trial Protocol

Iranian Registry of Clinical Trials

07 Jun 2026

The Comparison of skin grafts harvested from wrist area versus groin area in patients with finger tip injury referring to Imam Reza Hospital during the year 2014 to 2015

Protocol summary

Summary

In this study we compare wrist and groin harvested finger tip skin grafts to find out which site suits best finger tip skin defects. Seventy two patients in need of finger tip skin grafting aged twenty to seventy years old with no neuropathic disorders are randomized to a 36-patient group with skin graft harvested from the wrist or another 36-patient group with skin graft harvested from the groin. All the patients will be operated by one technique (full-thickness skin graft). The minimum follow up would be eighteen months. The intervention in this study would be skin grafting from two different sites, wrist area and groin area. The grafted skin between the two groups will be evaluated clinically regarding two point discrimination (T.P.D) with Dellon-McKinnon Disk-Criminator, light touch with Semmes-Weinstein monofilaments aesthesiometer, ulcer, graft contracture, hair growth on the grafted skin, and color difference between the graft and recipient site with Photoshop Analyzer Program. The significancy of mean differences in both groups will be compared statistically

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014110413259N1**

Registration date: **2014-12-01, 1393/09/10**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2014-12-01, 1393/09/10

Registrant information

Name

Farzam Mokarami

Name of organization / entity

Artesh University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Artesh University of Medical Sciences

Expected recruitment start date

2013-03-21, 1392/01/01

Expected recruitment end date

2014-03-20, 1392/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Comparison of skin grafts harvested from wrist area versus groin area in patients with finger tip injury referring to Imam Reza Hospital during the year 2014 to 2015

Public title

evaluation of skin grafts harvested from wrist area versus groin area

Purpose

Treatment

Inclusion/Exclusion criteria

-The inclusion criteria: normal sensation and judgment, and age between twenty and seventy years old. -The

exclusion criteria: patients with neuropathic disorders including diabetes, autoimmune diseases (eg; sclerodermia), congestive heart failure, chronic liver diseases, chronic renal failure, peripheral vascular diseases and smokers

Age

From **20 years** old to **70 years** old

Gender

Both

Phase

0

Groups that have been masked

No information

Sample size

Target sample size: **72**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

The patients will be randomized to a Wrist group or Groin group with a number allocated by Research Randomizer Program.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shiraz University of Medical Sciences

Street address

Palestine St., Zand Blvd.

City

Shiraz

Postal code

14336-71348

Approval date

2013-02-14, 1391/11/26

Ethics committee reference number

ct.p.91.2611

Health conditions studied

1

Description of health condition studied

Injuries to the wrist and hand

ICD-10 code

S60, S61,

ICD-10 code description

Superficial injury of wrist and hand, Open wound of wrist and hand , Crushing injury of wrist and hand , Other and unspecified injuries of wrist and hand

Primary outcomes

1

Description

Skin Color

Timepoint

Before surgery and at least six months afterwards

Method of measurement

Brightness of the skin will be measured by PhotoShop software after taking photos of the grafted area and data will be collected in a questionnaire

2

Description

Contracture

Timepoint

Before surgery and at least six months afterwards

Method of measurement

The proportion of the grafted area to the area of the primary injury will be calculated and data will be collected in a questionnaire

3

Description

Light Touch

Timepoint

Before surgery and at least six months afterwards

Method of measurement

Semmes-Weinstein monofilaments aesthesiometer with different thicknesses data will be collected in a questionnaire

4

Description

Hair Follicle Counts

Timepoint

Before surgery and at least six months afterwards

Method of measurement

The counts of hair follicles in the grafted area and data will be collected in a questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Skin grafts from wrist area (group1): We harvested the adjusted skin graft from the wrist area in elliptical form to incorporate to the size of the loss region in finger tips and tried to remove the subcutaneous fat completely to

increase the odds of successful grafting. No meshing procedure were used, Grafts were fixed with absorbable 4.0 (Vicryl, Ethicon Inc, New Jersey) running sutures. Then dressing was applied on by 4-layered sterile gauze in a moderately tight fashion. and due to the low risk of hematoma formation the grafts were seen after 5-7days.

Category

Treatment - Surgery

2

Description

Skin grafts from groin area (group2): We harvested the adjusted skin graft from the groin area in elliptical form to incorporate to the size of the loss region in finger tips and tried to remove the subcutaneous fat completely to increase the odds of successful grafting. No meshing procedure were used, Grafts were fixed with absorbable 4.0 (Vicryl, Ethicon Inc, New Jersey) running sutures. Then dressing was applied on by 4-layered sterile gauze in a moderately tight fashion. and due to the low risk of hematoma formation the grafts were seen after 5-7days.

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Nemazee Hospital

Full name of responsible person

Dr. Behdad Eskandari

Street address

Nemazee Square

City

Shiraz

2

Recruitment center

Name of recruitment center

Imam Reza hospital

Full name of responsible person

Dr. Farzam Mokarami

Street address

Etemadzade St., West Fatemi St.

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Shiraz University of Medical Sciences

Full name of responsible person

Dr. Basir Hashemi

Street address

Palestine St., Zand Blvd.

City

Shiraz

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, Shiraz University of Medical Sciences

Proportion provided by this source

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

2

Sponsor

Name of organization / entity

Vice chancellor for research, Artesh University of Medical Sciences

Full name of responsible person

Dr. Kamran Azma

Street address

Etemad Zadeh St., West Fatemi St.

City

Tehran

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, Artesh University of Medical Sciences

Proportion provided by this source

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

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Full name of responsible person

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Fax**Email**

Farzam_m2001@yahoo.com

Web page address**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty