Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Comparison of split thickness skin grafts and flaps in bilateral chronic axillary hidradenitis suppurativa: a prospective clinical trial

Protocol summary

Study aim

We aimed to compare the results of split thickness skin grafts (STSG) and flaps in patients with chronic bilateral axillary hidradenitis suppurativa.

Design

The protocol of this study was approved by Vice-Chancellor for Research and Technology of Shahid Beheshti University of Medical Sciences, Tehran, Iran. All consents were obtained by surgical residents and attending physicians. The non-randomized clinical trial was consisted of 30 patients with bilateral axillary hidradenitis suppurativa who would undergone graft or flap surgery.

Settings and conduct

The study took place in Shohadaye Tajrish hospital. In this study blinding technique was not applicable.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age between 18-70 years old, diagnosis of bilateral axillary hidradenitis suppurativa, American Society of Anesthesiology classes I and II, having informed consent to enter the study.

Intervention groups

The intervention group was 30 patients who were scheduled for first debridement. Wide excision of axillary hidradenitis was conducted. Then, a wet to dry depressing was applied.The patients were scheduled for their second operation to cover bilateral axillary wounds with split thickness skin grafts and flaps. An appropriate size STSG was harvested from anterior of right thigh in all patients to cover left axillary region. Right axillary wound was covered by fasciocutaneous flap taken from para-scapular region. The place of taking flap was repaired primarily. Dressings of the graft site were uncovered after five to six days and dressings of the flap sites were uncovered on the postoperative day one.

Main outcome variables

Complete recovery of the sides of graft and flap; recurrence; patients' satisfaction; symmetry and cosmetics; return to work; pain on flap or graft site; pain on flap or graft region

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20191019045155N2**
Registration date: **2020-01-23, 1398/11/03**
Registration timing: **retrospective**

Last update: **2020-01-23, 1398/11/03**
Update count: **0**

Registration date

2020-01-23, 1398/11/03

Registrant information

Name
Negin Yavari

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 21 8802 9600

Email address
negin.yavarii@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2010-03-01, 1388/12/10

Expected recruitment end date

2015-04-01, 1394/01/12

Actual recruitment start date

2010-03-21, 1389/01/01

Actual recruitment end date

2015-03-20, 1393/12/29

Trial completion date

2015-03-20, 1393/12/29

Scientific title
Comparison of split thickness skin grafts and flaps in bilateral chronic axillary hidradenitis suppurativa: a prospective clinical trial

Public title
Tissue coverage in axillary hidradenitis suppurativa
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Age between 18 and 70 years old Diagnosis of bilateral axillary hidradenitis suppurativa American Society of Anesthesiology classes of I and II Having informed consent to enter the study
Exclusion criteria:
Age
From **18 years** old to **70 years** old
Gender
Male

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **30**
Actual sample size reached: **30**
Randomization (investigator's opinion)
Not randomized
Randomization description
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Shahid Beheshti University of Medical Sciences
Street address
Shahid Beheshti University, Shahid Shahriari Square, Daneshjou Boulevard, Shahid Chamran Highway, Tehran, Iran
City
Tehran
Province
Tehran
Postal code
1985717443
Approval date
2010-02-01, 1388/11/12
Ethics committee reference number
M-233

Health conditions studied

1

Description of health condition studied
Axillary hidradenitis suppurativa
ICD-10 code
L73.2
ICD-10 code description
Hidradenitis suppurativa

Primary outcomes

1

Description
complete recovery of the sides of graft and flap
Timepoint
The patients were followed-up for one year and then were visited on a regular basis. At first one month after surgery then three, six and twelve months after their second operation.
Method of measurement
by visiting the patients and examining

2

Description
Recurrence
Timepoint
The patients were followed-up for one year and then were visited on a regular basis. At first one month after surgery then three, six and twelve months after their second operation.
Method of measurement
by visiting the patients and examining

3

Description
Patient's satisfaction
Timepoint
The patients were followed-up for one year and then were visited on a regular basis. At first one month after surgery then three, six and twelve months after their second operation.
Method of measurement
by visiting the patients and examining

4

Description
Range of motion of the shoulder
Timepoint
The patients were followed-up for one year and then were visited on on a regular basis. At first one month after surgery then three, six and twelve months after

their second operation.

Method of measurement

by visiting the patients and examining

5

Description

Pain on side or region of the flap or graft

Timepoint

The patients were followed-up for one year and then were visited on a regular basis. At first one month after surgery then three, six and twelve months after their second operation.

Method of measurement

Universal Pain Assessment Tool (UPAT)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: One group of 30 patients that received split thickness graft on left side and flap on right side after debridement of chronic bilateral axillary hidradenitis suppurative. The graft for the left side was harvested from anterior of right thigh and the flap was taken from para-scapular region. Dressings of the graft site were uncovered after five to six days and dressings of the flap sites were uncovered on the postoperative day one. The control and intervention groups were in the same person (left and right side).

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Shohada-Tajrish hospital

Full name of responsible person

Abolfazl Afsharfard

Street address

Tajrish Sq., Tehran, Iran

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Tehran

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1989934148

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Pr_shohada@sbmu.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Dr. Seyed Ali Ziaei

Street address

Tajrish Sq., Tehran, Iran

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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

Abolfazl Afsharfard

Position

Professor of surgery

Latest degree

Subspecialist

Other areas of specialty/work

Vascular surgeon

Street address

Tajrish Sq., Tehran, Iran

City

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

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Position

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Person responsible for updating data

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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

Not applicable

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

Not applicable

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

All the data will be available under the name of supplementary.

When the data will become available and for how long

All the data will be available after the publication of the article forever

To whom data/document is available

Data will be available to everybody upon request

Under which criteria data/document could be used

Data could be used by other researchers for meta-analysis and systematic review

From where data/document is obtainable

Data will be available as a supplementary file to the published article

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

The data will be available upon request, forever.

Comments