

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Sep 2026

Regeneration of human skin by adipose-derived stem cells (ADSC) cultured on scaffold

Protocol summary

Summary

Principal goal of study is to evaluate regeneration of human skin by adipose-derived stem cells (ADSC) cultured on scaffold. Specific goals are ability to extract ADSCs from autologous fat in human and proliferating and differentiating them in vitro in a scaffold covered with a silicon layer to prevent wound infection and evaluate their take after applying on deep burn area regarding clinical and histopathology parameters of wound healing. Design of this study is double blinded in which included 30 patients are assigned with third degree burn less than 30% TBSA who are admitted in a Motahari referral burn center. Patients are randomized into two groups of case and control with 15 patients in each. Exclusion criteria are non-thermal burns >30%BSA and association with inhalation injury, patients below 15 and over 50, Diabetics and other systemic conditions that impairs wound healing, Multiple organ failure and those with clinical and/or par clinical signs and symptoms of wound infection (SIRS). Prepared scaffold with and without ADSCs processed from autologous fat are applied in the burn wounds covered by a silicon sheet by a blinded surgeon. Wounds are biopsied after first, 3rd and 12th weeks and evaluate for clinical and histopathological criteria of wound healing. Outcome analysis would be done by SPSS.

General information

Acronym

ADSC:Adipose cell Derived Stem Cell

IRCT registration information

IRCT registration number: **IRCT201202169044N1**

Registration date: **2012-07-05, 1391/04/15**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2012-07-05, 1391/04/15

Registrant information

Name

Kamran Asadi

Name of organization / entity

Tehran University of Medical Sciences, Motahari Burn Center

Country

Iran (Islamic Republic of)

Phone

+98 21 8887 6226

Email address

asadi_kamran@tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences Vice Chancellor for research & Pasture Institute

Expected recruitment start date

2012-07-22, 1391/05/01

Expected recruitment end date

2013-01-20, 1391/11/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Regeneration of human skin by adipose-derived stem cells (ADSC) cultured on scaffold

Public title

Adipose Cell Derived Stem Cell application in deep burn healing

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criterion: third degree deep burn patients with less than 30% TBSA involvement. Exclusion criteria: 1. Non thermal burns and association with inhalation injury. 2. Patients below 15 y and above 50 y. 3. Diabetics and those with systemic conditions that impairs wound healing. 4. Multiple organ failure (respiratory, renal, etc...). 5. Wound infection. 6. SIRS : Include: fever >38c or hypothermia. >36c ,.Tachycardia >90 ppm, locoytosis WBC>4000 or Locopenia <1200, bandemia >10%.

Age

From **15 years** old to **50 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Tehran university ethics committee in research

Street address

No.21, 1st floor, Dameshgh St., Felestin St.,
Keshavarz blv.

City

Tehran

Postal code

tumspr@tums.ac.ir

Approval date

2010-04-17, 1389/01/28

Ethics committee reference number

90-03-12-12509-47883

Health conditions studied

1

Description of health condition studied

Deep Burn

ICD-10 code

T21.3

ICD-10 code description

Burn of third degree of trunk

Primary outcomes

1

Description

Vascularization

Timepoint

At the en of third week

Method of measurement

Number of blood vessels counted by digital camera in millimeter

2

Description

Collagen Number

Timepoint

At the end of third week

Method of measurement

Counting collagen bundles under microscope

3

Description

Collagen maturity

Timepoint

At the end of third week

Method of measurement

Ratio of mature collagen bundles to the whole collagen in the wound garding in low, moderate, high

4

Description

Granulation

Timepoint

at the end of third week

Method of measurement

Fibroplasia and angiogenesis in the wound beed grading in low, moderate and high.

5

Description

Epithelialization

Timepoint

At the end of third week

Method of measurement

Epithelialization density is graded in low , moderate and high

6

Description

Inflamation

Timepoint

At the end of third week

Method of measurement

Inflammatory cells infiltration density garding in low, modarate and high

7

Description

Graft take

Timepoint

1, 3 and 12 week

Method of measurement

Clinical judgment

Secondary outcomes

1

Description

Wound infection

Timepoint

1, 3 and 12 week

Method of measurement

Appearance of wound

Intervention groups

1

Description

Intervention: Prepared scaffold with ADSCs processed from autologous fat are applied in the burn wounds covered by a silicon sheet and would healing would be monitored then after.

Category

Treatment - Surgery

2

Description

Control : Prepared scaffold without ADSCs in control group is applied in the burn wounds and covered by a silicon sheet .

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Motahari Burn Center

Full name of responsible person

Dr. Kamran Asadi

Street address

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences, Vice chancellor for research

Full name of responsible person

Dr. Masoud Yunesian

Street address

1st Floor, No.21, Dameshgh St.,Felestin St., Keshavarz BLV.

City

Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Tehran University of Medical Sciences, Vice chancellor for research

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

Iran Pasteur Institute, Cell bank division

Full name of responsible person

Dr. Mohammad ali Shokrgozar

Street address

Iran Cell Bank, Iran Pasteur institute, 12 Farvardin st., Pasteur st., Tehran

City

Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Iran Pasteur Institute, Cell bank division

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

Hazrat Fatemeh Hospital

Full name of responsible person

Kamran Asadi

Position

University Board Member, Assistant professor

Other areas of specialty/work**Street address**

21st Street, Usefabad, Asad abadi st., Hazrat
Fatemeh Hospital

City

Tehran

Postal code**Phone**

+98 21 8871 7272

Fax**Email**

asadi_kamran@tums.ac.ir

Web page address**Email**

asadi_kamran@tums.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Hazrat Fatemeh Hospital

Full name of responsible person

Amin Adhami

Position

Plastic Surgery Resident

Other areas of specialty/work**Street address**

21st Street, Usefabad, Asad abadi st., Hazrat
Fatemeh Hospital

City

Tehran

Postal code

1433933111

Phone

+98 21 8871 7272

Fax

+98 21 8871 5216

Email

amin_414@yahoo.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Hazrat Fatemeh Hospital

Full name of responsible person

Kamran Asadi

Position

Assistant professor

Other areas of specialty/work**Street address**

21st Street, Usefabad, Asad abadi st., Hazrat
Fatemeh Hospital

City

Tehran

Postal code

1433933111

Phone

+98 21 8871 7272

Fax

+98 21 8871 5216

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