

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 May 2026

The study of using medical honey compared to stapler(Advan disposable skin stapler) for skin graft fixation in burn wounds

Protocol summary

Study aim

Determining the effect of using medical honey compared to stapler(Advan disposable skin stapler) in attaching skin grafts to burn wounds

Design

Clinical trial on 80 patients in addition of group control and in order to randomize the treatment between the groups, the 4 permutation blocks randomization.

Settings and conduct

The study population is all patients undergoing skin graft surgery admitted by the Velayat Burns Hospital. Skin graft surgery in 2 groups, using honey and using a stapler are included in the study. Comparison of honey group with stapler in terms of pain and itching, skin graft rejection, post-graft infection, graft skin displacement, creation hematoma, shrinkage of the skin and edema after transplantation

Participants/Inclusion and exclusion criteria

Inclusion criteria: All patients with second-degree and third-degree of burn wounds need a graft and burns with less than 40% which are performed in one step.

Exclusion criteria:Grafts that are performed in several stages and people with debilitating diseases and defected immune system, diabetes and Cortone users and head, face, neck injury and joints burned cases which are sensitive to honey and its derivatives.

Intervention groups

Two groups will be studied by honey and stapler used. In the first group, honey is used to attach the skin graft to the underlying tissue and in the second group, the stapler is used to attach the skin graft to the underlying tissue.

Main outcome variables

Evaluation and observation of the effectiveness of honey and stapler, Skin graft rejection, post-transplant infection, displacement of graft skin, hematoma, skin shrinkage, edema, pain and itching.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210524051384N2**

Registration date: **2021-10-14, 1400/07/22**

Registration timing: **prospective**

Last update: **2021-10-14, 1400/07/22**

Update count: **0**

Registration date

2021-10-14, 1400/07/22

Registrant information

Name

mohammadreza mobayen

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 13 3336 8540

Email address

maziar.mobayen@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-11-22, 1400/09/01

Expected recruitment end date

2022-12-22, 1401/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The study of using medical honey compared to stapler(Advan disposable skin stapler) for skin graft fixation in burn wounds

Public title

The effect of using medical honey on the attachment of skin grafts

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

All patients with deep grade 2 and 3 of burn wounds who need a graft and burns with less than 40% which are performed in one- step.

Exclusion criteria:

Grafts that are performed late and in several stages and people with debilitating diseases and defected immune system, diabetes and Cortone users and burns injuries on the head, face, neck ,joints and allergies to honey and its products.

Age

From **20 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

In order to randomize the treatment between the groups, 4 permutation blocks method will be used. Group A is the intervention group and group B is the control group, and data randomization was performed with SAS software version 9.

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

Research Ethic Committees of Guilan University of Medical science

Street address

Guilan University of Medical science

City

Rasht

Province

Guilan

Postal code

4144666949

Approval date

2021-09-29, 1400/07/07

Ethics committee reference number

IR.GUMS.REC.1400.304

Health conditions studied

1

Description of health condition studied

Burns

ICD-10 code

Z94.5

ICD-10 code description

Skin transplant status

Primary outcomes

1

Description

Efficiency of honey in attaching skin grafts

Timepoint

Duration of hospitalization

Method of measurement

By observing skin graft area and experienced burn specialist's opinion

Secondary outcomes

1

Description

Evaluating the degree of displacement of grafted skin

Timepoint

On fifth, seventh and fourteenth days after surgery

Method of measurement

Based on millimeters

2

Description

Infection after skin graft surgery

Timepoint

On seventh, fourteenth and one month after surgery

Method of measurement

Based on culture and Antibioqram

3

Description

Hematoma

Timepoint

On fifth, seventh and fourteenth days after surgery

Method of measurement

By observing the accumulation of blood outside the vessels around the skin graft

4

Description

The amount of pain

Timepoint

At 3, 6, 12 and 24 hours and by the third day after surgery

Method of measurement

Using the VAS criteria

5

Description

Itching

Timepoint

At 3, 6, 12 and 24 hours and by the third day after surgery

Method of measurement

Through the 5-D criterion based on the length, severity, recovery and disability degree caused by itching.

6

Description

Edema

Timepoint

On fifth, seventh and fourteenth days after surgery

Method of measurement

By observing the abnormal accumulation of interstitial fluid water under the skin graft and observing by professionals

7

Description

Shrinkage of the skin graft

Timepoint

On fifth, seventh and fourteenth days after surgery

Method of measurement

Based on millimeters (length and width)

8

Description

Follow-up of transplantation

Timepoint

On fifth, seventh and fourteenth days after surgery

Method of measurement

Based on discoloration of transplanted skin and photography and observing by burn specialist's opinion

9

Description

Duration of hospitalization

Timepoint

Duration of patients' hospitalization

Method of measurement

Day

Intervention groups

1

Description

Intervention group: Using honey instead of stapler to attach skin grafts. The medical honey used in this study is (Madi Hani) honey gel available in the market which is free from all the harms of ordinary honey to preserve all the properties of honey, including enzymes and diastases. Honey is refined at temperatures below 50 degrees. This honey has a low pH and high osmolarity with high antibacterial properties against the spectrum. A wide range of resistant strains along with maintaining the ideal moisture of the wound environment plays an effective role in healing. Patients with second and third deep grad of burn wounds require a graft, with burns less than 40% that are done in a single step that requires an autograft skin graft from the patient after the necessary and sufficient explanations about the study and the procedure for patients by an expert and physician and obtaining informed consent from 80 patients who are candidates for skin graft surgery using honey, which is removed from the patient with a skin dermatome device and placed in the appropriate area.

Category

Treatment - Drugs

2

Description

Control group: the use of stapler in attaching skin grafts. A stapler will be used to attach the skin graft to the underlying tissue. Using Advan disposable skin stapler which is disposable and is provided by Farab Surgeon Company, which is made and sterilized by the factory and is disposed of after use. Patients with second and third deep grad of burn wounds require a graft, with burns less than 40% that are done in a single step that requires an autograft skin graft from the patient after the necessary and sufficient explanations about the study and the procedure for patients by an expert and physician and obtaining informed consent from 80 patients who are candidates for skin graft surgery using honey, which is removed from the patient with a skin dermatome device and placed in the appropriate area

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

Velayat Hospital

Full name of responsible person

Mohammadreza Mobayen

Street address

Parastar Street, Namjo Street

City

Rasht

Province

Guilan

Postal code

4193713194

Phone

+98 13 3336 8540

Email

maziar.mobayen@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Rasht University of Medical Sciences

Full name of responsible person

Dr. Mohammadreza Naghipour

Street address

Deputy of Research and Technology, in front of 17
Shahrivar Hospital, Namjo St.,

City

Rasht

Province

Guilan

Postal code

4193713191

Phone

+98 13 3333 6394

Email

research@gums.ac.ir

Web page address

Grant name

Grant code / Reference number

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

No

Title of funding source

Vice-Chancellor for Research, Guilan University of
Medical Sciences

Proportion provided by this source

100

Public or private sector

Private

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

Rasht University of Medical Sciences

Full name of responsible person

Dr.mohammadreza Mobayen

Position

Fellowship in Plastic Surgery

Latest degree

Subspecialist

Other areas of specialty/work

General Surgery

Street address

Velayat Hospital, Namjo Street

City

Rasht

Province

Guilan

Postal code

4193713194

Phone

+98 13 3336 8540

Email

maziar.mobayen@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Rasht University of Medical Sciences

Full name of responsible person

Dr.Mohammadreza Mobayen

Position

Fellowship in Plastic Surgery

Latest degree

Subspecialist

Other areas of specialty/work

General Surgery

Street address

Velayat Hospital, Namjo Street

City

Rasht

Province

Guilan

Postal code

4193713194

Phone

+98 13 3336 8540

Email

maziar.mobayen@gmail.com

Person responsible for updating data

Contact

Name of organization / entity

Rasht University of Medical Sciences

Full name of responsible person

Alale Jarrahi

Position

Professional PhD student

Latest degree

Medical doctor

Other areas of specialty/work

General Practitioner

Street address

Velayat Hospital, Namjo Street

City

Rasht

Province

Guilan

Postal code

4193713194

Phone

+98 13 3336 8540

Email

alalejarrahi.1995@gmail.com

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

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

Undecided - It is not yet known if there will be 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

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

Data Dictionary

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