Clinical Trial Protocol
Iranian Registry of Clinical Trials

29 May 2026

The effect of traditional dressing and aminiotic dressing on facial abrasion repair: a randomized control trial

Protocol summary

Study aim
The effect of traditional dressing and amniotic dressing on the repair of facial superstructuration

Design
This study is a prospective clinical trial consisting of 24 patients with facial abrasion, which will be conducted by oral and maxillofacular surgery (OMFS) of Velayat and Poursina hospitals during 1401. The transplant method used (traditional or amniotic membrane) will be explained in detail for each patient individually, including benefits, disadvantages, and informed written consent will be taken from everyone. Patients will be randomly divided into two groups (each group of 13 patients). A group of people receiving standard or traditional treatment (control group). And the other group of people whose wounds will be covered with amniotic membrane and will be treated (intervention group). In the amniotic group, the transplant will be placed on the wound bed and then the dressing will be performed for 2 weeks. Amniotic membrane sticks to the wound bed when placed on the wound and there will be no need for stitches. Patients will be examined by an OMFS specialist on days 4, 7, 14 and 30 and the thickness of scars will be evaluated by Vancouver scar scale. Itching ratings from 0 (no itching) to 4 (severe itching) will be done by the same specialist. The collected data will be analyzed in IBM SPSS Statistics software version 26 at a significant level of 5%.

Settings and conduct
Velayat Burn Center

Participants/Inclusion and exclusion criteria
Patient with facial abrasion

Intervention groups
Patient with facial abrasion. In this group, patients are candidates for traditional dressing and amniodon dressing.

Main outcome variables
The intensity of itching, degree of pain, and incidence of infection (days 4, 7, 14)

General information

Reason for update

Acronym
HAM

IRCT registration information
IRCT registration number: **IRCT20221116056518N1**
Registration date: **2022-11-29, 1401/09/08**
Registration timing: **registered_while_recruiting**

Last update: **2022-11-29, 1401/09/08**
Update count: **0**

Registration date
2022-11-29, 1401/09/08

Registrant information

Name
Rahman Hosseini Karizomr

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 21 7795 8432

Email address
s.rahman.hosseiny@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-11-22, 1401/09/01

Expected recruitment end date
2023-02-20, 1401/12/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effect of traditional dressing and aminiotic dressing on facial abrasion repair: a randomized control trial

Public title
Facial abrasions and amniotic membrane
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
... Emergency department admission less than 24 hours after the incident Satisfaction with participating in the study Ages between 18 and 60 Facial ulcers at least 15% of the surface of the skin on the patient's face
Exclusion criteria:
late referral history of heart, kidney, diabetes and other metabolic organs (e.g. thyroid, pituitary, etc.)
Age
From **18 years** old to **60 years** old
Gender
Both

Phase
4
Groups that have been masked
No information
Sample size
Target sample size: **44**
Randomization (investigator's opinion)
Randomized
Randomization description
In this study, in order to allocate patients to intervention and control groups, resticted randomization approach will be used in parallel with block randomization method. We will consider the blocks as a 4-size random. The allocation ratio of samples will be (1:1) and will be in two groups of control and intervention. Then, based on the obtained blocks and sequencing, allocation of dressings will be placed on patients in the control and intervention group. To generate random numbers, various packages in R software will be used.
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Guilan University of Medical Sciences
Street address
namjoo street, rasht, guilan
City
Rasht
Province
Guilan
Postal code
1111-1111
Approval date
2022-11-09, 1401/08/18
Ethics committee reference number
IR.GUMS.REC.1401.409

Health conditions studied

1

Description of health condition studied
Facial abrasion
ICD-10 code
T14.0
ICD-10 code description
Superficial injury of unspecified body region

Primary outcomes

1

Description
The intensity of itching
Timepoint
(days 4, 7, 14)
Method of measurement
Itching ratings from 0 (no itching) to 4 (severe itching) will be done by the same specialist

2

Description
degree of pain
Timepoint
(days 4, 7, 14)
Method of measurement
Pain Score on a scale of one to ten by patients

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: This study is a prospective cohort consisting of 24 patients with ulcers, which will be conducted by the Department of Oral and Maxillofacial Surgery (OMFS) of Porsina Hospital during the year 1401. The method of implantation used (conventional or amniotic membrane) will be explained in detail to each patient individually, including advantages, disadvantages, and written informed consent will be obtained from all. Patients will be randomly divided into

2 groups (12 people in each group). A group of people receiving standard or traditional treatment (control group). and another group of people whose wound will be covered with amniotic membrane and treated (intervention group). Permission for all stages of this study will be obtained from the university ethics committee. In the intervention group, after cleaning the wound surface with normal saline serum and separating foreign bodies (if any), washing with 0.9% normal saline and then biological dressing (amnion) will be done. Amnion biological surrogate (mother's pair) is used for non-diseased and healthy mothers after elective caesarean section in Al-Zahra Hospital. According to health protocols for mothers, blood samples are sent to the laboratory to check for HCV, HBS and HIV. The embryonic layers of the placenta are separated under the hood and then washed under sterile conditions with Ringer's solution, and the amnion layer is separated and transferred to sterile containers (4°C). In order to remove blood and other contaminants, it is washed four times with normal saline and then once with 0.25% sodium hypochlorite solution and washed again with normal saline. Then the samples are transferred to the refrigerator in sterile containers.To rule out bacterial contamination, routine cultures are performed from the stored membranes. Amniotic curtains should be prepared no later than 12 hours after delivery, and after freezing and drying, they can be stored for about a year. Regarding the placement of the amnion membrane, care must be taken to ensure that the lower layer, which has the ability to multiply, is placed on the wound and that the tissue is not placed on the wound from behind. Then dressing will be done for 2 weeks on days 4, 7 and 14. When the amniotic membrane is placed on the wound, it will stick to itself and there will be no need for stitches. Pieces of amniotic membrane measuring 1-2 x 3-5 cm can be selected depending on the size and extent of the wound.Patients will be examined by an OMFS specialist at intervals of 1 month, 2 months, and 6 months, and the thickness of the scars will be evaluated with the Vancouver scar scale (VSS). Also, the rating of itching from 0 (no itching) to 4 (severe itching) will be done by the same expert.

Category

Treatment - Surgery

2

Description

Control group: In this study, the control group will receive standard treatment. This treatment includes using gentamicin ointment or tetracycline for decontamination, sutures if necessary, and then covering wounds with wet-to-dry dressing in this method after one week, the dressing is removed and after pulling the sutures, the person will be prescribed anti-scar ointment.

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Velayat Burn Center

Full name of responsible person

Rahman Hosseini Karizomr

Street address

Velayat Hospital, Namjoo Street, Rasht, Guilan

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Rasht University of Medical Sciences

Full name of responsible person

Mohammadreza Naghipour

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

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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

Rasht 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
Rasht University of Medical Sciences

Full name of responsible person
Rahman Hosseiny kariz omar

Position
Resident of oral and maxillofacial surgery

Latest degree
Medical doctor

Other areas of specialty/work
Dentistry

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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)
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
Not applicable

Informed Consent Form
No - There is not a plan to make this available

Clinical Study Report
Not applicable

Analytic Code
Not applicable

Data Dictionary
Not applicable