Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Comparison of the effects of biological (amniotic) with traditional dressings in the treatment of deep second degree burn wounds 5-20% in less than 24 hours in patients admitted to the Velayat hospital

Protocol summary

Study aim

Comparison of the effect of biological dressings (amniotic fluid) with traditional dressings in the treatment of second-degree thermal burn wounds of less than 24 hours 5 - 20% in patients referred to the burn hospital of the province.

Design

In this study, to assign patients to intervention and control groups, the Restricted randomization approach will be used in parallel with the random block method. We will consider blocks of random size of 4. Random Allocation software will be used to generate random numbers. In this study, blinding will not occur due to the different appearance of biological (amniotic) and traditional dressings.

Settings and conduct

In this study, to compare the effect of biological dressings (amniotic fluid) with traditional dressings in treating burn wounds less than 24 hours, second-degree depth of 5-20% in patients referred to the provincial hospital, all eligible patients will be included in the study. In this study, blinding will not occur due to the different appearance of biological (amniotic) and traditional dressings.

Participants/Inclusion and exclusion criteria

Inclusion criteria: • Satisfaction with participation in the study • Age 18 to 60 years • Grade 2 burns with 5-20% • No grade 3 burns • Admission less than 24 hours from the occurrence of burns • Heat burns with boiling water or flammable materials • No underlying diseases
Exclusion criteria: • Death of the patient • Dissatisfaction with continuing the study • Impossibility to follow the patient treatment process

Intervention groups

Intervention group 1: biological dressings (amniotic fluid) and group 2: traditional dressings

Main outcome variables

Pain rate; Itching rate; Average number of dressings; Incidence of infection; Duration of hospitalization; recovery time in days

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210524051384N1**
Registration date: **2021-08-24, 1400/06/02**
Registration timing: **prospective**

Last update: **2021-08-24, 1400/06/02**
Update count: **0**

Registration date

2021-08-24, 1400/06/02

Registrant information

Name
mohammadreza mobayen

Name of organization / entity

Country
Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-09-23, 1400/07/01

Expected recruitment end date

2022-09-22, 1401/06/31

Actual recruitment start date

empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison of the effects of biological (amniotic) with traditional dressings in the treatment of deep second degree burn wounds 5-20% in less than 24 hours in patients admitted to the Velayat hospital

Public title
Comparison of the effects of biological (amniotic) with traditional dressings in the treatment of deep second degree burn wounds 5-20% in less than 24 hours in patients admitted to the Velayat hospital
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Age 18 to 60 years Grade 2 burns Burns that are greater than 20 to 25 percent Admission less than 24 hours from the occurrence of burns Thermal burns with boiling water or flammable substances No underlying diseases such as diabetes, immune system deficiency, connective tissue disease, kidney disease, liver disease and hepatitis, etc. Satisfaction of participating in the study
Exclusion criteria:
Age over 60 years Patients who died during the study Dissatisfaction with continuing the study Impossibility to follow the patient treatment process
Age
From **18 years** old to **60 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **42**
Randomization (investigator's opinion)
Randomized
Randomization description
Blocking and allocation sequences will be done by the person not involved in the research to hide the patient's choice. The sample allocation ratio will be (1: 1) and will be divided into control and intervention groups. Then, based on the obtained blocks and in the order of allocation, the dressings will be placed on the patients of the control and intervention groups. In this study, blinding will not occur due to the different appearance of biological (amniotic) and traditional dressings. In this study, to assign patients to intervention and control groups, the limited randomization approach will be used in parallel with the block randomization method. We will consider random blocks of size 4. A table of random numbers (Random allocation software) will be used to generate random numbers.
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 Ethics Committees Of Guilan University Of Medical Sciences
Street address
Guilan University Of Medical Science
City
Rasht
Province
Guilan
Postal code
4144666949
Approval date
2021-07-28, 1400/05/06
Ethics committee reference number
IR.GUMS.REC.1400.177

Health conditions studied

1

Description of health condition studied
Acute burn
ICD-10 code
T30
ICD-10 code description
Burn and Corrosion, Body Region Unspecified

Primary outcomes

1

Description
Average recovery time
Timepoint
daily
Method of measurement
Based on disease course / percentage

Secondary outcomes

empty

Intervention groups

1

Description

biological dressing: For patients with grade 2 burns, in group A, after cleaning the burned surface and removing blisters and foreign objects from the burn site, washing with normal saline will be performed, and then biological dressing (amniotic fluid) will be served. The amniotic biological dressing is prepared from a pair of healthy mothers after a selective cesarean section at Al-Zahra Hospital. According to health protocols for mothers, blood samples are sent to the laboratory for testing for HCV, HBS, and HIV. The embryonic-related layers of the placenta are separated under the hood and then washed under sterile conditions with Ringer's solution. The amniotic layer is separated and transferred to cold sterilized containers (4 ° C). to remove the blood and other contaminants, it will be washed four times with normal saline. Once with 0.25% sodium hypochlorite solution, and washed again with normal saline. Then, the samples are transferred to sterile containers and refrigerated. When placing the amniotic membrane, care should be taken; that the underlying layers, which can reproduce, should be placed on the wound.

Category

Treatment - Other

2

Description

B) Traditional dressings: In group B, dressings will be applied in a traditional and daily manner according to the protocol of the Velayat hospital. After washing the wound with normal saline and debridement if necessary, ointments (Flamazine, Adiazine ،Mafenaide, Sulfamylon) are applied to the wound and then with plain gas. Will be covered and dressed.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Velayat hospital

Full name of responsible person

Amirmohammad Gholipour

Street address

Velayat Hospital, Namjoo St. , Rasht, Guilan, Iran

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Province

Guilan

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Email

velayathospital@gmail.com

Web page address

https://www.gums.ac.ir/velayat

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Deputy of Research and Technology, Guilan University of Medical Sciences

Full name of responsible person

Dr Mohammadreza Naghipour

Street address

Namjoo St, in front of 17 Shahrivar Hospital, Deputy of Research and Technology, Rasht, Guilan, Iran

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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

Other

Person responsible for general inquiries

Contact

Name of organization / entity

Guilan University Of Medical Sciences

Full name of responsible person

Ammirmohammad Gholipour

Position

Medical Student

Latest degree

A Level or less

Other areas of specialty/work

Medical Education

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Person responsible for scientific inquiries

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A Level or less
Other areas of specialty/work
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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
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