

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

The effect of amniotic membrane in healing of burn wounds in comparison with Ag coat dressing in the burned patients in Isfahan burn center

Protocol summary

Study aim

A study for evaluation of each burn dressing efficacy in Isfahan University of Medical Sciences.

Design

This study is a phase 2 clinical trial has two parallel arms, double blind and randomized by minimization method; in each group 25 patients will be evaluated.

Settings and conduct

This study is a phase 2 clinical trial with a control group and in parallel, double-blind, randomized with minimization process. There are 25 patients in each group.

Participants/Inclusion and exclusion criteria

Inclusion criteria is all of patients aged 1 to 60 years old with 2nd degree higher burn and exclusion criteria's are anemia; pregnancy; lactation; multiple trauma and chronic disease.

Intervention groups

There are two groups in this study. Respectively we use ag-coat and amniotic membrane in first and second groups for burned wound covering.

Main outcome variables

Burn degree; burn surface; the Vancouver scar scale; hospitalization; treatment cost

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210705051792N1**

Registration date: **2021-11-01, 1400/08/10**

Registration timing: **registered_while_recruiting**

Last update: **2021-11-01, 1400/08/10**

Update count: **0**

Registration date

2021-11-01, 1400/08/10

Registrant information

Name

Amin Ghanei Anaraki

Name of organization / entity

Country

Iran (Islamic Republic of)

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Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-07-23, 1400/05/01

Expected recruitment end date

2022-02-19, 1400/11/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of amniotic membrane in healing of burn wounds in comparison with Ag coat dressing in the burned patients in Isfahan burn center

Public title

The effect of amniotic membrane in compare of Agcoat in healing of burn wounds

Purpose

Health service research

Inclusion/Exclusion criteria

Inclusion criteria:

Second Degree or More Burn Patient informed consent to participate in the study Exclusion criteria: Associated Trauma Associated Chronic Illness Pregnancy Lactation Age From 1 year old to 60 years old Gender Both Phase N/A Groups that have been masked • Participant • Care provider • Outcome assessor • Data analyser • Data and Safety Monitoring Board	Street address Hezar Jarib Ave., Isfahan University of Medical Sciences City Isfahan Province Isfahan Postal code 81746-73461 Approval date 2021-06-25, 1400/04/04 Ethics committee reference number IR.MUI.MED.REC.1399.736
Sample size Target sample size: 25 Randomization (investigator's opinion) Randomized Randomization description In this study random sequence generation perform as minimization and for this manner initially the first case allocated to the first group and the second case also allocated to another group. According to the features of each cases a matched case also choice and include to the groups. For concealment, the cases will be added as lottery. Blinding (investigator's opinion) Double blinded Blinding description Before transfer to the operation room. It is explained for the patients that their burn ulcer will be dressed as one of two formal manner. In operating room after allocation of each cases to groups finally, dressing will be done. Even after surgery, the patients do not aware of dressing type. In day 7, the patients` dressing will be changed by a nurse who do not participate in the study and the patient will be refer to a researcher(who do not aware of dressing type) for evaluation of variables and these variables will be send for analysis. Placebo Not used Assignment Parallel Other design features	Health conditions studied <u>1</u> Description of health condition studied Burn ICD-10 code T30.0 ICD-10 code description Burn of unspecified body region, unspecified degree
Secondary Ids empty Ethics committees <u>1</u> Ethics committee Name of ethics committee Ethics committee of isfahan University of Medical Sciences	Primary outcomes <u>1</u> Description The Vancouver Scar Scale Timepoint First week, First month, Third month, Sixth Month Method of measurement According to Chart and Scale between 0-13 <u>2</u> Description Hospitalization Timepoint From admission to discharge Method of measurement The days according to hospitalization file since the first day to the discharge day <u>3</u> Description Treatment cost Timepoint Admission Duration Method of measurement Cost in Rials based on the final bill of the hospital Secondary outcomes empty Intervention groups

1

Description

Control group: In this group of patients, after initial resuscitation of burns, in the operating room, according to the extension of the burn, for one session or more, the burnt tissues will be debrided to reach a viable level. The burn wound will be covered by the Ag-coat dressing - Emad brand (which is the brand used by the hospital) as a standard and accepted treatment. Normally, a silver dressing is effective for 7 to 10 days, after which time it will be removed and based on the wound condition, a decision is made on how to continue the treatment, including repetition of the Ag-coat dressing, skin graft, or regular dressing. Finally, three, six and twelve months after the onset of burn, the patient's wound is evaluated according to clinical criteria as well as the Vancouver chart.

Category

Treatment - Other

2

Description

Intervention group: In this group of patients, after initial resuscitation of burns, in the operating room, based on the extension of the burn, for one session or more, the burnt tissues will be debrided to reach a viable level. The Life Cell brand (which is the brand used by the hospital) is covered as a new treatment. The amniotic dressing is usually absorbed within 5 to 7 days, after which time the condition of the wound is decided on how to continue the treatment, including skin grafts or regular dressings. Finally, three months and six months after the onset of burn, the patient's wound is evaluated according to clinical criteria as well as the Vancouver chart.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Isfahan Burn Center

Full name of responsible person

Amin Ghanee Anaraki

Street address

Isfahan Burn Center, Kave Ave.

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Web page address

<https://savaneh.mui.ac.ir/>

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Sara Arti

Street address

Esfahan University of Medical Sciences, Hezar Jarib

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Isfahan

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81746-73461

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research@mui.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Esfahan 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

Esfahan University of Medical Sciences

Full name of responsible person

Amin Ghanee Anaraki

Position

Plastic Surgeon

Latest degree

Subspecialist

Other areas of specialty/work

Plastic Surgery

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Second Floor, Savaneh hospital, Kave

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

Majid Kalbasi Gharavi

Position

Plastic Surgery Fellowship

Latest degree

Specialist

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Person responsible for updating data

Contact

Name of organization / entity

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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

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is 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

Yes - There is a plan to make this available

Title and more details about the data/document

Except of Personal Information of patients all of other is reachable

When the data will become available and for how long

Every 3 months

To whom data/document is available

Academic Researcher

Under which criteria data/document could be used

Academic Research

From where data/document is obtainable

Study Correspondent

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

Request by E-Mail

Comments