

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

A comparative study on the efficacy and safety of temporary cover wound dressing with Agi coat in comparison with allograft (cadaver) in burn patients admitted to Imam Musa Kazem Hospital in Esfahan.

Protocol summary

Study aim

Comparison of efficacy and safety of temporary burn wound dressing with Ajicoat compared to allograft

Design

Patients were divided into two groups (25 people in each group) control (dressing with ajikot) and experimental group (dressing with cadaver). The sampling method was that the first sample entered in the study was placed in the experimental group and the next sample in the control group. Did we

Settings and conduct

This clinical trial was performed after approval by the ethics committee of Isfahan University of Medical Sciences and receiving permission and obtaining written consent from patients. In order to conduct the research, the researcher first referred to Imam Musa Kazem (AS) Hospital with a written letter of introduction from the research deputy and after explaining the process and objectives of the research, attracted the cooperation of the officials. This study is a clinical trial and prospective. In total, 50 burn patients who met the inclusion criteria were included in this study after filling out the consent form.

Participants/Inclusion and exclusion criteria

Patients in the age group of 18-45 years with 20-30% burns and deep grade 2 and 3 were identified. These patients had at least 12 mg per 100 cc and serum protein at least 6 mg per 100 cc at baseline

Intervention groups

جهت پانسمان گروه کنترل از اجی کوت و گروه آزمون از کاداور استفاده شد که نحوه درمان بدین صورت بود که در اتاق عمل پس از دبریدمان، روی زخمها با اجی کوت یا کاداور که در گلیسرول 85% بود، پوشانده شد و قبل از استفاده از کاداور آن را بمدت 10 دقیقه با نرمال سالین شستشو داده تا غلظت گلیسرین موجود در آن به کمتر از 1% برسد.

Main outcome variables

Wound infection rate,Debridement rate,The amount of

pain

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190807044468N1**

Registration date: **2020-11-19, 1399/08/29**

Registration timing: **retrospective**

Last update: **2020-11-19, 1399/08/29**

Update count: **0**

Registration date

2020-11-19, 1399/08/29

Registrant information

Name

fateme hadadi sohi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3345 7672

Email address

hadadesoh94@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-08-08, 1397/05/17

Expected recruitment end date

2019-12-01, 1398/09/10

Actual recruitment start date

2018-08-08, 1397/05/17

Actual recruitment end date

2019-12-01, 1398/09/10

Trial completion date

2019-12-01, 1398/09/10

Scientific title

A comparative study on the efficacy and safety of temporary cover wound dressing with Agi coat in comparison with allograft (cadaver) in burn patients admitted to Imam Musa Kazem Hospital in Esfahan.

Public title

The effect of ajicoat and cadaver on burn treatment

Purpose

Diagnostic

Inclusion/Exclusion criteria**Inclusion criteria:**

Patients in the age group of 18-45 years with 20-30% burns and deep grade 2 and 3 were identified. These patients had at least 12 mg per 100 cc and serum protein at least 6 mg per 100 cc at baseline

Exclusion criteria:

More than 48 hours had passed since their burns.

Age

From **18 years** old to **45 years** old

Gender

Both

Phase

1-2

Groups that have been masked

No information

Sample size

Target sample size: **50**

Actual sample size reached: **50**

Randomization (investigator's opinion)

Not randomized

Randomization description**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**

Ethics committee of Esfahan University of medical Sciences

Street address

Kaveh Avelmam Musa Kazem Hospital in Esfahan.,

City

Esfahan

Province

Isfahan

Postal code

81388-94999

Approval date

2018-09-16, 1397/06/25

Ethics committee reference number

IR.MUI.RESEARCH.REC.1397.198

Health conditions studied**1****Description of health condition studied**

burn and corrosion

ICD-10 code

T31.2

ICD-10 code description

Burns involving 20-29% of body surface

Primary outcomes**1****Description**

Wound debridement rate

Timepoint

Measure pain and debridment and infection from day one to day thirteen

Method of measurement

To collect samples, a checklist was used which consisted of two parts: the first part was related to patients' demographic information including age, sex, date and time of burn, depth and percentage of burn. The second section included information on morphine use, number of debridement surgeries, the patient's pain score in the postoperative days, and symptoms of wound infection.

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: For dressing the experimental group, cadaver was used. The treatment method was that in the operating room after debridement, the wounds were covered with cadaver, which was 85% glycerol and prepared from Iranian Tissue Products Company. Using Kadavar, rinse it with normal saline for 10 minutes to reduce the glycerin concentration to less than 1%. Serum tests for CMV-Ab: VDRL: HCV-Ag: HBS-Ag have been performed and approved for allografts. It is the Ministry of Health, and it is also made in Iran.

Category

Treatment - Surgery

2**Description**

Control group: Agicoat was used for dressing the control

group, which was treated in such a way that in the operating room, after debridement, the wounds were covered with Agi coat prepared by Sara Pars Pharmaceutical Company.

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Isfahan University of Medical Sciences-Imam Musa Kazem Hospital

Full name of responsible person

Fateme Hadadi Sohi

Street address

Kaveh St. - Imam Musa Kazem Hospital

City

Esfahan

Province

Isfahan

Postal code

81388-94999

Phone

+98 31 3345 7672

Email

hadadesoh94@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Shaghayegh Haghjoo Javanmard

Street address

Isfahan University of Medical Sciences.Vice-Chancellery for Research & Technology

City

Isfahan

Province

Isfahan

Postal code

81746-73461

Phone

+98 31 3792 3060

Email

sh_haghjoo@med.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

Fateme Hadadi Sohi

Position

Infection Control Expert

Latest degree

Master

Other areas of specialty/work

Nursery

Street address

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

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Person responsible for updating data

Contact

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

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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

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

No - There is not a plan to make this available

Title and more details about the data/document

Data on main outcomes

When the data will become available and for how long

2020

To whom data/document is available

Academic institutions

Under which criteria data/document could be used

For research

From where data/document is obtainable

Message to email

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

Message to email

Comments