

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 Jun 2026

comparison of the effectiveness of dry human amniotic membrane in secondary intention healing of full thickness and non-infected wounds of abdomen and genitalia following surgery or trauma in ICU patients

Protocol summary

Study aim

Evaluation of wound healing by using dry human amniotic membrane

Design

In this single-blind randomized clinical trial, patients with genitalia and abdominal open wounds who are candidate for secondary intention wound healing, were randomly assigned to two groups (at least 20) via sealed envelopes and in one group first post operative dressing were done with dry human amniotic membrane and the other days wounds were dressed routinely and in the other group the wounds were dressed routinely without using amniotic membrane till patients discharged

Settings and conduct

All patients in Shohada Tajrish hospital and Imam Reza hospital with genitalia and abdominal open wounds who are candidate for secondary intention wound healing enrolled in this one side blind(patients) study, through sealed envelope patients were randomized to two groups and the effect of dry human amniotic membrane and routine wound dressing without amniotic membrane on wound healing of patients was compared

Participants/Inclusion and exclusion criteria

The patients >30 years old that have abdominal or genitalia open wound and candidate for secondary intention wound healing include in study and patients with infected wound or whom do not complete consent form exclude from study

Intervention groups

In one group the first dressing of wound was done with dry human amniotic membrane and for the next times till hospital discharge dressing was done routinely and in the other group wound was dressed routinely without amniotic membrane

Main outcome variables

situation of open wound healing time to heal open wound

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180218038788N2**

Registration date: **2020-06-16, 1399/03/27**

Registration timing: **registered_while_recruiting**

Last update: **2020-06-16, 1399/03/27**

Update count: **0**

Registration date

2020-06-16, 1399/03/27

Registrant information

Name

amirhossein rahavian

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2271 8000

Email address

amirrahavian@sbm.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-01-21, 1398/11/01

Expected recruitment end date

2020-11-21, 1399/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

comparison of the effectiveness of dry human amniotic membrane in secondary intention healing of full thickness and non-infected wounds of abdomen and genitalia following surgery or trauma in ICU patients

Public title

effect of dry human amniotic membrane in wound healing

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

age more than 30 y/o Any underlying problem that may interfere with the tissue repair process including Diabetes. Immune deficiency diseases. Connective tissue disorders. heavy smoking or any other lung or heart disease that disrupts the oxygen supply to the tissue Full thickness open wounds in the genital area and Perineum that due to inflammation, wound contamination or huge defect are not suitable candidates for primary healing Aforementioned wounds that were repaired once and again for various reasons including hematoma, High tension on the repair site, Inappropriate blood supply and ... has been restored and cannot be repaired in the second time Aforementioned wounds that are candidate for secondary intention based of physician opinion

Exclusion criteria:

active wound infection lack of consent form completion by patient patient death during study

Age

From 30 years old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant

Sample size

Target sample size: 20

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization was done from a computer-generated sequence(SAS software), concealed in sequentially numbered, sealed, opaque envelopes, and kept by the ward secretary

Blinding (investigator's opinion)

Single blinded

Blinding description

after explanation of study, all the participants are blind because patients divided to two groups by sealed envelops and same intervention was done for both groups but with different material.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of AJA University of Medical Sciences

Street address

Tehran, West Fatemi Ave., Shahid Etemadzade Ave., AJA University of Medical Sciences

City

Tehran

Province

Tehran

Postal code

1411718541

Approval date

2020-05-26, 1399/03/06

Ethics committee reference number

IR.AJAUMS.REC.1399.053

Health conditions studied

1

Description of health condition studied

wound

ICD-10 code

S31

ICD-10 code description

Open wound of abdomen, lower back, pelvis and external genitals

Primary outcomes

1

Description

wound healing time

Timepoint

14-30-90 days

Method of measurement

physical examination by physician

Secondary outcomes

1

Description

wound infection rate

Timepoint

14-30-90 days

Method of measurement

wound culture

2

Description

hospital admission time

Timepoint

14-30-90 days

Method of measurement

admission and discharge date

Intervention groups

1

Description

Intervention group: On the first or second day after surgery or trauma, if the wound is not infectious, a dry human amniotic membranes are placed on the wound and dressing is performed.

Category

Treatment - Other

2

Description

Control group: On the first or second day after surgery or trauma, if the wound is not infectious, the dressing is done routinely without an amniotic membrane.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Shohada Tajrish hospital

Full name of responsible person

Amirhossein Rahavian

Street address

Shohada Tajrish Hospital, Shahr-dari Ave., Tajrish Square, Teharn

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amirrahavian@yahoo.com

2

Recruitment center

Name of recruitment center

Imam Reza Hospital

Full name of responsible person

Amirhossein Rahavian

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Imam Reza Hospital, Etemadzadeh Ave., West Fatemi street, Tehran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Artesh University of Medical Sciences

Full name of responsible person

Ramin Hamidi

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West Fatemi Ave., Etemadzade Street, Artesh University of Medical Science

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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

Artesh 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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Amirhossein Rahavian

Position

Resident
Latest degree
Medical doctor
Other areas of specialty/work
Urology
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Person responsible for scientific inquiries

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is 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

Title and more details about the data/document

There is no further information

When the data will become available and for how long

There is no further information

To whom data/document is available

There is no further information

Under which criteria data/document could be used

There is no further information

From where data/document is obtainable

There is no further information

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

There is no further information

Comments