Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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 envelops 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

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amirrahavian@sbmu.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, Shahrdari Ave., Tajrish Square, Teharn
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1989934148
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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
Street address
West Fatemi Ave., Etemadzade Street, Artesh University of Medical Science
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amirrahavian1369@gmail.com
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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Shohada Tajrish Hospital, Shahrdari Ave., Tajrish Square, Tehran
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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