Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

The effect of human umbilical cord whartons jelly stem cells cultured on amniotic membrane on chronic wound healing

Protocol summary

Study aim

The purpose of this study was to use the Whartons Jelly mesenchymal stem cells on amniotic membrane to help repair it for the treatment of chronic skin ulcers.

Design

The clinical trial with a community-based control and parallel groups that are assigned by random numbers. Each group consists of 5 patients.

Settings and conduct

All patients will subjected weekly to standard wound treatment consisted of disinfection, debridement when needed, and application of advanced wound dressing and bandages. The wounds will covered by acellular amniotic membrane seeded with WJSCs for 9 days, every 3 days with a follow up of one month. The percentage and time of wound healing, and the size of wound injury will recorded for each patient. A picture will taken from each lesion at the onset of the study (T0), and after 3, 6, and 9 days post-treatment (T3, T6, T9). The wound size at T0 will determined and the wound closure rate was obtained by dividing the ulcer size at T0 by the number of days needed for healing (cm2/day).

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age between 20-60 years old; Chronic wound less than 1% of the body surface due to vascular causes (arterial, venous and lymphatic), diabetic, radiotherapy, subcutaneous wound Exclusion criteria: Pregnant Women ; Any patients that is treated with medications causes wound healing, malignancy, or osteomyelitis in the wound

Intervention groups

Intervention group: The amniotic membrane with mesenchymal stem cells will be used Control group: Amniotic curves will be used alone.

Main outcome variables

Wound surface

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20090128001605N18**
Registration date: **2020-01-18, 1398/10/28**
Registration timing: **retrospective**

Last update: **2020-01-18, 1398/10/28**
Update count: **0**

Registration date

2020-01-18, 1398/10/28

Registrant information

Name
Ali Akbar Mohammadi
Name of organization / entity
Shiraz University of Medical Sciences
Country
Iran (Islamic Republic of)
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+98 71 1621 6097
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mohamadiaa@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-11-22, 1397/09/01

Expected recruitment end date

2019-02-20, 1397/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
The effect of human umbilical cord whartons jelly stem cells cultured on amniotic membrane on chronic wound healing

Public title
The effect of mesenchymal stem cells on amniotic membrane
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Age between 20-60 years old Chronic wound less than 1% of the body surface due to vascular causes (arterial, venous and lymphatic), diabetic, radiotherapy, subcutaneous wound
Exclusion criteria:
Pregnant Women Any patients that is treated with medicine that causes wound healing disorder, malignancy, or osteomyelitis in the wound
Age
From **20 years** old to **60 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **15**
Randomization (investigator's opinion)
Randomized
Randomization description
Individuals are assigned to each of the groups using a random number table with simple randomization method. Random numbers are generated by computers that randomly adjust the digits, then the researcher give each member of the community a special code or number, then consider the even number for one group, and odd number for other group.
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 Shiraz University of Medical Sciences
Street address
Shiraz University of Medical Sciences, Zand Blvd
City
Shiraz
Province
Fars
Postal code
۱۴۳۳۶- ۷۱۳۴۸
Approval date
2016-03-07, 1394/12/17
Ethics committee reference number
IR.SUMS.REC.1394.51

Health conditions studied

1

Description of health condition studied
Chronic wound
ICD-10 code
L98.4
ICD-10 code description
Chronic ulcer of skin, not elsewhere classified

Primary outcomes

1

Description
Wound surface
Timepoint
The wounds will covered by acellular amniotic membrane seeded with WJSCs for 9 days, every 3 days with a follow up of one month.
Method of measurement
Pellany Metric Software

Secondary outcomes

1

Description
The duration of wound healing
Timepoint
The wounds will cover by acellular amniotic membrane seeded with WJSCs for 9 days, every 3 days with a follow up of one month.
Method of measurement
Days

Intervention groups

1

Description
intervention group: In this group, patients wound will be closed with an amniotic membrane with mesenchymal stem cells and covered for 9 days, every 3 days with a follow up of one month. The percentage and time of wound healing and the size of wound injury will be recorded for each patient. A picture will take from each lesion at the onset of the study (T0), and after 3, 6, and 9

days' post-treatment (T3, T6, T9). The wound size at T0 will be determined and the wound closure rate was obtained by dividing the ulcer size at T0 by the number of days needed for healing (cm2/day). The dressing method used in this study by the use of mesenchymal stem cells of umbilical cord from the selected cesarean section at 36th and 37th weeks of gestation. The tissues will be transferred to the lab at 4 ° C as soon as surgery is performed in aseptic conditions in a sterile saline phosphate buffer containing 50 µg / ml streptomycin and 50 µg / ml penicillin 50 µg / ml., Then the amniotic membrane is separated by mechanical method from the chorion of placenta and is washed several times with a cold saline phosphate buffer of 4 ºC. Wharton jelly beans are removed gently and transferred to a PBS container. Wharton jelly fragments are fragmented with scalps. The components in the T25 flask containing DMEM, 5% human serum (HS) and antibiotic (penicillin/streptomycin) (1%) will be transferred to the incubator at 37 ° C, humidity 95% and 5% CO2, and after 3 days, of the flask medium will be replaced. After filling the flask floor, the cells will pass through the trypsin 0.25%, after the second passage, 15-20 million cells are transferred to the scapula of the new amniotic fluid (epithelial surface) as a scaffold and It will be used to cover the patients' wound with chronic ulcers.

Category

Treatment - Other

2

Description

Control group: The patients wound will be closed with cell-free amnion and covered for 9 days, every 3 days with a follow up of one month. The percentage and time of wound healing, and the size of wound injury will be recorded for each patient. A picture will take from each lesion at the onset of the study (T0), and after 3, 6, and 9 days' post-treatment (T3, T6, T9). The wound size at T0 will determined and the wound closure rate was obtained by dividing the ulcer size at T0 by the number of days needed for healing (cm2/day).All patients will be subjected weekly to standard wound treatment consisted of disinfection, debridement when needed, and application of advanced wound dressing and bandages.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Ghadir Mother and Child Hospital

Full name of responsible person

Ali Akbar Mohammadi

Street address

New Quran Blvd, in Golshan Town

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Email

burns1@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Younes Ghasemi

Street address

Vice-chanceller of Research Shiraz University of Medical Sciences; Central department of Shiraz University of Medical Sciences, Zand Blvd

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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

Shiraz 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

Shiraz University of Medical Sciences

Full name of responsible person

Ali Akbar Mohammadi

Position

Associate Professor, General Surgeon

Latest degree

Specialist

Other areas of specialty/work

General Surgery
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Training center for burn injuries amiralmomenin, Km 2 Sadra
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Person responsible for scientific inquiries

Contact
Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Seyedeh-Sara Hashemi
Position
Assistant Professor
Latest degree
Ph.D.
Other areas of specialty/work
Histology
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Training center for burn injuries amiralmomenin, Km 2 Sadra
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Fax
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Web page address

Person responsible for updating data

Contact
Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Masoomeh Kherad
Position
Manager of Shiraz Burn Reaserch Center/Bachelor of Nursing
Latest degree
Bachelor
Other areas of specialty/work
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Training center for burn injuries amiralmomenin, Km 2 Sadra
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Postal code
7198754361
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burnres1@sums.ac.ir
Web page address

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