

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

01 Jun 2026

### The use of dressings containing autologous conditioned serum as a new method for the treatment of chronic ulcers

#### Protocol summary

##### Study aim

Determination the effect of dressings containing autologous conditioned serum as for the treatment of chronic ulcers

##### Design

Two arm parallel-group concealed, randomized, blinded placebo-controlled phase 3 clinical trial of 30 patients, enrolled between August 2019 and March 2020

##### Settings and conduct

Thirty diabetic patients with a chronic ulcer at Imam Reza Hospital in Tabriz undergo wound dressing with autologous conditioned serum or normal saline for 5 weeks. Random allocation will be done by random blocking method using 4 and 8 blocks and RASS software and 1: 1 allocation ratio. The two dressings have no different in appearance. Principal investigators, clinical caregivers, outcome assessors and data analysts and reviewers will have no information about study group allocations by the end of the study.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Type 1 or 2 Diabetes Mellitus and Wagner grading of lesions 1 or 2 not healing for at least 3 months Exclusion criteria: Wagner grading of lesions 3 or 4, active infection of the lesion, hemorrhagic disorders and major large vessel disease

##### Intervention groups

Intervention 1: Dressing containing autologous conditioned serum that is replaced once a week for 5 weeks Intervention 2: Dressing containing saline normal that is replaced once a week for 5 weeks

##### Main outcome variables

Ulcer size

#### General information

##### Reason for update

To increase the generalizability of the results and conduct a timely trial

##### Acronym

#### IRCT registration information

IRCT registration number: **IRCT20100720004422N7**

Registration date: **2019-08-15, 1398/05/24**

Registration timing: **prospective**

Last update: **2021-07-03, 1400/04/12**

Update count: **1**

#### Registration date

2019-08-15, 1398/05/24

#### Registrant information

##### Name

Seyed Kazem Shakouri

##### Name of organization / entity

Tabriz University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 41 1336 3518

##### Email address

shakourik@tbzmed.ac.ir

#### Recruitment status

**Recruitment complete**

#### Funding source

#### Expected recruitment start date

2019-08-23, 1398/06/01

#### Expected recruitment end date

2020-03-19, 1398/12/29

#### Actual recruitment start date

empty

#### Actual recruitment end date

empty

#### Trial completion date

empty

#### Scientific title

The use of dressings containing autologous conditioned serum as a new method for the treatment of chronic ulcers

**Public title**

Effect of autologous conditioned serum on the chronic wounds

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

Wagner grading of lesions 1 or 2 not healing for at least 3 months

**Exclusion criteria:**

Wagner grading of lesions 3 or 4 Active infection of the lesion Hemorrhagic disorders Platelet disorders Major large vessel disease

**Age**

From **18 years** old to **80 years** old

**Gender**

Both

**Phase**

2-3

**Groups that have been masked**

- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

**Sample size**

Target sample size: **30**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Simple randomization method through computer-generated random numbers by an independent statistician with the allocation ratio of 1:1

**Blinding (investigator's opinion)**

Single blinded

**Blinding description**

It is not possible to blind the participants to treatment. Furthermore, the treating physicians will not blind to the treatment; however, investigators providing treatment will be different from those performing wound evaluations, and the persons responsible for clinical tests and also the statistician who will execute all the statistical analysis will be blind to study group allocation.

**Placebo**

Used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Ethics committee of Tabriz University of Medical Sciences

**Street address**

Research Vice Chancellor, Tabriz University of Medical Sciences, Daneshgah Ave.

**City**

Tabriz

**Province**

East Azarbaijan

**Postal code**

5789766788

**Approval date**

2019-05-06, 1398/02/16

**Ethics committee reference number**

IR.TBZMED.REC.1398.154

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

Chronic ulcer

**ICD-10 code**

L99

**ICD-10 code description**

Other disorders of skin and subcutaneous tissue in diseases classified elsewhere

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

Ulcer healing

**Timepoint**

Wound size measurement at baseline (before intervention) and 21 days after dressing

**Method of measurement**

Pressure Ulcer Scale for Healing Includes the extent of the wound, the presence of exudates and the appearance of the wound

**Secondary outcomes**

empty

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

Intervention group: Dressing containing autologous conditioned serum that is replaced once a week for 3weeks. To prepare the autologous conditioned serum, fifty milliliters of blood will be drawn from ante-cubital vein of the patients into a blood bag and be transferred to an autoclaved centrifuge tube without anticoagulants. Blood will be incubated aseptically at 37 C° for 24 hours. After incubation the tubes will be centrifuged at 3500 rpm for 10 minutes to retrieve the autologous conditioned serum. A clinical research coordinator will educate the patients about wound care and when to return for dressing replacement.

**Category**

Treatment - Drugs

**2**

**Description**

Control group: Dressing containing saline normal that is replaced once a week for 3 weeks

**Category**

Treatment - Drugs

**Recruitment centers**

**1**

**Recruitment center**

**Name of recruitment center**

Emam Reza hospital

**Full name of responsible person**

Seyed Kazem Shakouri

**Street address**

Emam Reza hospital, Golgasht Str., Azadi Ave.

**City**

Tabriz

**Province**

East Azarbaijan

**Postal code**

5163995479

**Phone**

+98 41 3336 1928

**Email**

skshakouri@gmail.com

**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Tabriz University of Medical Sciences

**Full name of responsible person**

Abolghasem Jooyban

**Street address**

Research Vice Chancellor, Tabriz University of Medical Sciences, Daneshgah Ave.

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research-vice@tbzmed.ac.ir

**Grant name**

**Grant code / Reference number**

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

Yes

**Title of funding source**

Tabriz 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**

Tabriz University of Medical Sciences

**Full name of responsible person**

Seyed Kazem Shakouri

**Position**

Professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Physical Medicine

**Street address**

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**Phone**

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**Contact**

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## Person responsible for updating data

### Contact

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### Email

skshakouri@gmail.com

## 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