

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Effect of Autologous Platelet Gel on healing of cutaneous Leishmaniosis wounds

Protocol summary

Study aim

Determination of the effect of Autologous Platelet Gel on wound healing and repair of scars caused by cutaneous Leishmaniasis

Design

In this clinical trial, 15 patients entered the study according to entry requirements and randomly. In this clinical trial, a wound that received routine treatment in addition to the platelet gel, is compared with another wound on the patient's hand that received only routine treatment. This study is the third phase of the trial. In this intervention, platelet gel is used at 5 time points (Once a week) for each patient.

Settings and conduct

The place of the intervention is Jahrom University of Medical Sciences. In this study, the physician is blind to the type of treatment.

Participants/Inclusion and exclusion criteria

The subjects are patients with cutaneous leishmaniasis. Entry requirements: Patients with cutaneous leishmaniasis, Age between 15 to 50 years old. Non-entry: Hypovolemic states, Qualitative and quantitative platelet dysfunction, Sepsis, Diabet

Intervention groups

The intervention group consists of patients who have ulcers caused by cutaneous leishmaniasis with the entry conditions mentioned above, and in addition to routine treatment (glucantime), they will receive the autologous platelet gel product. The control group receive only routine treatment.

Main outcome variables

Duration of wound healing, Wound area

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190212042694N1**

Registration date: **2019-02-20, 1397/12/01**

Registration timing: **registered_while_recruiting**

Last update: **2019-02-20, 1397/12/01**

Update count: **0**

Registration date

2019-02-20, 1397/12/01

Registrant information

Name

Akbar Hashemi Tayer

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 71 5434 0405

Email address

a.hashemi@jums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-02-20, 1397/12/01

Expected recruitment end date

2019-08-23, 1398/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of Autologous Platelet Gel on healing of cutaneous Leishmaniosis wounds

Public title

Effect of platelet gel on healing of leishmaniosis wound

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Patients with cutaneous leishmaniasis referring to health centers

Exclusion criteria:
Hypovolumic patients Qualitative and quantitative
Platelet disorders Sepsis Diabet

Age
From **15 years** old to **50 years** old

Gender
Both

Phase
3

Groups that have been masked

- Care provider
- Outcome assessor

Sample size
Target sample size: **15**
More than 1 sample in each individual
Number of samples in each individual: **2**
Patients with cutaneous Leishmaniasis usually have more than one ulcers that can be selected the control group and the case in one person.

Randomization (investigator's opinion)
Randomized

Randomization description
In this study, patients are selected randomly
Randomization unit: Individual

Blinding (investigator's opinion)
Double blinded

Blinding description
In this study, clinical observant and outcome evaluator are not aware of the type of treatment given in each group and are actually Blind to those who received the platelet gel.

Placebo
Not used

Assignment
Parallel

Other design features
Patients are randomly assigned into two groups (control-case). The control group, are received the routine treatment and the case group, received a platelet gel in addition to the routine treatment.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethics

Street address

Jahrom university of medical sciences, Mothahri Ave,
Jahrom city, Fars province

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Fars

Postal code

7414846199

Approval date

2018-08-01, 1397/05/10

Ethics committee reference number

IR.JUMS.REC.1397.033

Health conditions studied

1

Description of health condition studied

Cutaneous Leishmaniosis

ICD-10 code

B55.1

ICD-10 code description

Cutaneous leishmaniasis

Primary outcomes

1

Description

Size of the wound

Timepoint

Once a week after starting treatment, until the wound is completely healed

Method of measurement

Ruler

Secondary outcomes

1

Description

Determination of the Effect of Platelet Gel on Cutaneous Leishmaniasis Wound Healing

Timepoint

Once a week after starting treatment

Method of measurement

Patient examination by physician

Intervention groups

1

Description

Intervention group: Includes people with cutaneous Leishmaniasis and between 15 and 50 years of old. In this group, in addition to the routine treatment, the autologous platelet gel is used once a week until complete wound healing.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Jahrom University of Medical Sciences, Ghafori Lab

Full name of responsible person

Akbar Hashemi Tayer

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Motahari Ave, Jahrom City, Fars Province, IRAN

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Jahrom University of Medical Sciences

Full name of responsible person

Kavous Solhjo

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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

Jahrom 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

Jahrom University of Medical Sciences

Full name of responsible person

Akbar Hashemi Tayer

Position

Assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Hematology

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Person responsible for scientific inquiries

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Person responsible for updating data

Contact

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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

No - There is not a plan to make this available