

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

assesment of immunomodulatory effect of β Glucan on wound healing ,A two parallel group randomized clinical trial

Protocol summary

Summary

The objective of this study is extraction of beta glucan from cell wall of fungi and using in cream form for wound healing in burn patients. The efficacy of this product in cream form will be evaluated during debridement and changing the dressing of wound. This Randomised clinical trial(phase 3) study will performed during 20 months in 124 patients with level 2 burn wound in . Care monitoring comprising closing and decreasing the wound size in first week of care,the third day and end of second week and finally end of treatment. Histopathology examination will perform for confirm of wound healing with preparation section from wound area,tissue staining and assessment tissue changing with light microscope.Also for estimating macrophage activity that play main role in wound healing,the end of treatment period in each group of patient (control and test),2-4 ml blood sample will collect the serum separate and inflammatory cytokine such as TNF α ,IFN γ ,IL1 assess by using ELISA kit and OD in control and test group will determine using ELISA reader. inclusion criteria are;the age of patients:18-50 years.burn classification: level 2 and <50% of body surface is burned.Gender;two gender(male , famale) Exclusion criteria: The women with pregnancy; the patients with immunodeficiency ;Liver and Kidney diseases. The patients including control and test groups.Treatment with local form of beta glucan continued at 8 week in test group.Although the two group receive silver sulfadiazine as base line care Primary outcome is Decrease at least 25% wound surface.Secondry outcome are measurement of INF γ ,IL1,TNF α .

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016020726411N1**

Registration date: **2016-03-14, 1394/12/24**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2016-03-14, 1394/12/24

Registrant information

Name

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Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Ministry of research and Technology,Iran University of Medical Science

Expected recruitment start date

2016-04-08, 1395/01/20

Expected recruitment end date

2018-04-09, 1397/01/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

assesment of immunomodulatory effect of β Glucan on wound healing ,A two parallel group randomized clinical trial

Public title

assessment of immunomodulatory effect of β Glucan on wound healing in burn patients

Purpose

Treatment

Inclusion/Exclusion criteria

According the similar studies in wound healing by using other imperious agents and attitude skin healing physician in motahari hospital, in this study inclusion criteria are;the age of patients:18-50 years.burn classification: second level and <50% of body surface is burned.Gender;two gender(male , famale) Exclusion criteria: the women with pregnancy; the patients with immunodeficiency, immunosuppression drug consumption; acute infections ;Liver and Kidney diseases .The pateints don't permit to enter the other clinical trial during this study.

Age

From **18 years** old to **50 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **124**

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Double blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features

According Block Randomization and regarding 4 blocks,31 block will produce for 124 patients

Secondary Ids

empty

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

Ethics committee of Iran University of Medical Sciences

Street address

Hemat west highway,intervention shikh fazollah nori and chamran

City

Tehran

Postal code**Approval date**

2015-10-07, 1394/07/15

Ethics committee reference number

IR.IUMS.REC.1394 - 26610

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

Burn wound

ICD-10 code**ICD-10 code description****2****Description of health condition studied**

Burn wound

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

Decrease at least 25% wound surface

Timepoint

decreasing the wound size in first week of care,the third day and end of second week and finally end of treatment

Method of measurement

centimeter

Secondary outcomes**1****Description**

TNF Alpha

Timepoint

End of study(8th week)

Method of measurement

ELISA and OD

2**Description**

IFN gamma

Timepoint

End of study(8th week)

Method of measurement

ELISA and OD

3**Description**

IL1

Timepoint

End of study(8th week)

Method of measurement

ELISA and OD

Intervention groups

1

Description

The patients divide two groups: The first one is control group that receive the usual wound care protocol (silver sulfadiazine)

Category

Treatment - Drugs

2

Description

The second group comprising patients that receive extracted beta Glucan in local form plus silver ointment

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Motahari Hospital

Full name of responsible person

Maryam Roudbary

Street address

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ministry of Research and Technology Iran University of Medical Science

Full name of responsible person

Dr seyed Ali Javad Mosavi

Street address

Hemat Highway, intervention shikh Fazollah and chamran, Iran University of Medical science, Ministry of research

City

Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Ministry of Research and Technology Iran University of Medical Science

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Iran university of Medical science

Full name of responsible person

Dr Maryam Roudbary

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Full name of responsible person

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Web page address**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty