Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Evaluation of efficacy and side effects of chitosan alginate dressings in chronic wound heal in patients refer to shohadaye tajrish hospital during two years

Protocol summary

Summary

In this trial chitosan and alginate which are produced in Europe are mixed with different proportions and chitosan-alginate dressing is formed.Then it is compared with traditional dressing used routinely in chronic ulcer treatment; these dressings are sterilized by different beams and then in open-label trial in Shohadaye Tajrish hospital, 32 patients are enrolled in our trial and randomely assigned to two groups. First group treated with chitosan-alginate dressing and the second one with traditional dressing. In first visit after gathering information we take photograph of their ulcer and dressing is placed and changes every 48-72 hours. In each visit photographs are taken from the ulcers. Follow up continuous until 4 weeks after healing of the ulcer. Images are evaluated by two dermatologists who are unaware of treatment groups and adverse effects and degree of remission are assessed.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016041927480N1**
Registration date: **2017-01-07, 1395/10/18**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2017-01-07, 1395/10/18

Registrant information

Name

Yasaman Ketabi

Name of organization / entity

Shahid beheshti university of medical science

Country

Iran (Islamic Republic of)

Phone

+98 22292895

Email address

yketabi@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Skin disease research center, Shohadaye Tajrish hospital

Expected recruitment start date

2016-09-19, 1395/06/29

Expected recruitment end date

2019-03-21, 1398/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of efficacy and side effects of chitosan alginate dressings in chronic wound heal in patients refer to shohadaye tajrish hospital during two years

Public title

Evaluation of efficacy and side effects of chitosan alginate dressings in chronic wound heal

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: age more than 18 years old; chronic wound with duration more than 4-6 weeks; wound diameter 1-200 square centimeter; consent for entering trial. Exclusion criteria: refuse to enroll; allergy to shellfish, lobster; attending other trials; pregnancy; lactation; severe co-morbidity; collagen vascular ulcers

or severe infected ulcers.

Age

From **18 years** old to **99 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **32**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Shahid Beheshti University of Medical Sciences

Street address

Shahid Beheshti University of Medical Sciences, Daneshjoo blvd., Velenjak

City

Tehran

Postal code

Approval date

2016-02-02, 1394/11/13

Ethics committee reference number

IR.SBMU.SRC.REC.1394.15

Health conditions studied

1

Description of health condition studied

Chronic ulcer

ICD-10 code

L98.4

ICD-10 code description

Chronic ulcer of skin, not elsewhere classified

Primary outcomes

1

Description

For chronic ulcer assessment of remission

Timepoint

Visit and photo taking each 2-3 days

Method of measurement

0-24...no improvement,25-49:...moderate improvement,50-74:significant improvement.....75-100:complete improvement

2

Description

Degree of erythema

Timepoint

Visit and photo taking each 2-3 days

Method of measurement

0: no erythema,1:pink,2:red

3

Description

Degree of exudate

Timepoint

Visit and photo taking each 2-3 days

Method of measurement

0:no 1:low 2: moderate-severe

4

Description

Degree of odor

Timepoint

Visit and photo taking each 2-3 days

Method of measurement

0:negative 1:positive

5

Description

Patient satisfaction

Timepoint

Visit and photo taking each 2-3 days

Method of measurement

Low noderate good excellent

Secondary outcomes

empty

Intervention groups

1

Description

32 patients are enrolled in our trial randomely assigned to two groups each has 16 patients first treated with chitosan-alginate dressing .

Category

Treatment - Other

2

Description

Second group consist of 16 patients treated with

convensional dressings that is silver sulfadiazine in this study

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Shohadaye Tajrish hospital

Full name of responsible person

Dr. Yasaman Ketabi

Street address

Shohadaye Tajrish hospital, between Tajrish and Qods squares

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice-Chancellor in Research Affairs, Shahid Beheshti University of Medical Sciences

Full name of responsible person

Dr Hamideh Moravej

Street address

Skin Research Center, Shohadaye Tajrish hospital, Tajrish square

City

Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice-Chancellor in Research Affairs, Shahid Beheshti University of Medical Sciences

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

Shohadaye Tajrish Hospital

Full name of responsible person

Dr. Yasaman Ketabi

Position

MD, dermatology resident

Other areas of specialty/work

Street address

Shohadaye Tajrish Hospital,Tajrish square

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yac_kt@yahoo.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Shohadaye Tajrish Hospital

Full name of responsible person

Dr. Fahime Abdollahi Majd

Position

Assistant professor

Other areas of specialty/work

Street address

Shohadaye Tajrish Hospital,Tajrish square

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Tehran

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Fax

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Fabdollahimajd@yahoo.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Shohadaye Tajrish Hospital

Full name of responsible person

Dr Yasaman Ketabi

Position

Dermatology resident

Other areas of specialty/work

Street address

Tehran,tajrish square,shohadaye tajrish hospital

City

Tehran

Postal code

Phone

Fax

Email

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