

Clinical Trial Protocol

Iranian Registry of Clinical Trials

12 Jul 2026

The effect of chitosan based prepared gel on healing Grade 2 and 3 wounds: A clinical trial study

Protocol summary

Study aim

Evaluation of wound healing effects using chitosan-based gel preparation in patients with grade 2 and 3 wounds and if positive results be obtained, this method can be used to reduce complications in patients with grade 2 and 3 wounds.

Design

In this study, all participants will enter the study after reviewing the inclusion criteria and obtaining informed consent. This study consists of 2 groups. The group treated with chitosan base gel (group 1) is performed in patients suffering from 2 and 3 grade wounds and dressing with sterile bilayer gas. In contrast, the control group (group 2) was treated with conventional

Settings and conduct

Molecular Medicine Research Center, Arak University of Medical Sciences, Sepahan and wound healing special clinic, Esfahan

Participants/Inclusion and exclusion criteria

Inclusion criteria: Suffering 2 and 3 grade wounds; Age range 18 to 60 years; Exclusion criteria: The patient has already or three months before the referral participated in another clinical trial study ; The patient is allergic to seafood.

Intervention groups

The group treated with chitosan base gel (group 1) is performed in patients suffering from 2 and 3 grade wounds and dressing with sterile bi-layer gas. In contrast, the control group (group 2) was treated with conventional methods.

Main outcome variables

Wound size, wound dept, wound healing time

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210510051243N2**

Registration date: **2022-04-03, 1401/01/14**

Registration timing: **prospective**

Last update: **2022-04-03, 1401/01/14**

Update count: **0**

Registration date

2022-04-03, 1401/01/14

Registrant information

Name

Hamid Abtahi

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 86 3417 3502

Email address

abtahi@arakmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-05-22, 1401/03/01

Expected recruitment end date

2023-02-20, 1401/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of chitosan based prepared gel on healing Grade 2 and 3 wounds: A clinical trial study

Public title

The effect of chitosan based prepared gel on healing Grade 2 and 3 wounds

Purpose

Health service research

Inclusion/Exclusion criteria

Inclusion criteria:

Suffering grade 2 and 3 wounds

Exclusion criteria:

The patient has already or three months prior to referral has participated in another clinical trial study. Presence of sensitivity to seafood

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

1

Groups that have been masked

No information

Sample size

Target sample size: **20**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients will be randomly assigned to two groups. To do this, the online Sealed envelope site will be used. Blocks of size 4 will be used. So that all possible sequences of two intervention and two control treatment in each block will be made with each block being numbered. Then, using random number table, the blocks will be selected randomly and the patients will be assigned to the two groups of intervention and control according to the blocks sequences

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

Arak University of Medical Sciences, Arak, Iran

Street address

A'lam-Al-Hoda Street, Shahid Shiroodi Street, Arak, Markazi Province, Iran

City

Arak

Province

Markazi

Postal code

۳۸۱۹۶۹۳۳۴۰

Approval date

2022-03-13, 1400/12/22

Ethics committee reference number

IR.ARAKMU.REC.1400.355

Health conditions studied

1

Description of health condition studied

grade 2 and 3 wounds

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

wound size

Timepoint

every week

Method of measurement

ruler

2

Description

wound healing time

Timepoint

every week

Method of measurement

counting days

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: groups treated with chitosan gel (group 1) in patient suffering from grade 2 and 3 wounds

Category

Treatment - Drugs

2

Description

Control group: patients suffering from grade 2 and 3 wounds receiving common treatments

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Sepahan Wound Health Specialized Clinic

Full name of responsible person

Hasan Jafari

Street address

Isfahan, Shohada Soffeh Blvd. Khanevadeh-Hospital-
Sepahan Wound Health Specialized Clinic

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

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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

Arak 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

Arak University of Medical Sciences

Full name of responsible person

Hamid Abtahi

Position

professor

Latest degree

Ph.D.

Other areas of specialty/work

Microbiology

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is 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

Yes - There is 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

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available

Title and more details about the data/document

The non-identifiable individual participant data collected
in this study will be shared. Also, The protocol, results,
and statistical analysis of the current study will be
published in the relevant articles.

**When the data will become available and for how
long**

The non-identifiable individual participant data will
become available after the publication of the relevant
articles.

To whom data/document is available

The non-identifiable individual participant data will
become available to other researchers in academic
institutions.

Under which criteria data/document could be used

The non-identifiable individual participant data can only
be used for research.

From where data/document is obtainable

The non-identifiable individual participant data will be
obtainable by sending an e-mail to Dr. Hamid Abtahi
(Email: abtahi@arakmu.ac.ir).

**What processes are involved for a request to access
data/document**

Other researchers in academic institutions can send their
request by e-mail to Dr. Hamid Abtahi (Email:
abtahi@arakmu.ac.ir). The data will be sent to them after
consulting and approving the research team.

Comments