

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Clinical study of wound healing caused by elective cesarean section using probiotic lysate in chitosan nano-gel base.

Protocol summary

Study aim

Treating wound caused by elective cesarean section using a new formulation compose of probiotic lysate in chitosan nano gel base

Design

Clinical trial with control group, parallel groups with 30 person per group, double blind and randomized with a random number table.

Settings and conduct

The study is being carried out at Hazrat Zeinab Hospital in Shiraz. After surgery, the patient applies the topical product on her wound twice daily, and the physician examines the relevant variables on days 0, 3, 7, 10, and 12. In this study, physician, researcher and patient are not aware of the type of product received.

Participants/Inclusion and exclusion criteria

Level of education should be at least fifth grade elementary school, The pregnancy period is between 37-42 weeks, don't have history of more than two cesareans and don't have drug sensitivity

Intervention groups

The intervention groups in this study will be probiotic based on chitosan nanogels, chitosan nanogels alone and the group receiving placebo.

Main outcome variables

The main variables studied in this study include redness, swelling, ecchymosis, discharge and wound area.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20130514013321N2**

Registration date: **2020-05-17, 1399/02/28**

Registration timing: **prospective**

Last update: **2020-05-17, 1399/02/28**

Update count: **0**

Registration date

2020-05-17, 1399/02/28

Registrant information

Name

Ahmad Gholami

Name of organization / entity

Shiraz University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 71 1242 4255

Email address

gholami@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-06-21, 1399/04/01

Expected recruitment end date

2021-01-20, 1399/11/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Clinical study of wound healing caused by elective cesarean section using probiotic lysate in chitosan nano-gel base.

Public title

The effect of probiotic on wound healing.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

The level of education should be at least a fifth-grade elementary school. The pregnancy period is between 37-42 weeks. The pregnancy period is between 37-42 weeks.

Exclusion criteria:
History of more than two cesareans. BMI of more than 35. Drug sensitivity.

Age
From **20 years** old to **35 years** old

Gender
Female

Phase
3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **90**

Randomization (investigator's opinion)
Randomized

Randomization description
Balanced block randomization

Blinding (investigator's opinion)
Double blinded

Blinding description
The control and intervention groups were randomly selected. The physician gives the medicine to the patients randomly. The researcher does not know about each group until after the analysis.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Shiraz University of Medical Sciences

Street address
Floor 7, Vice chancellor of research and technology, Shiraz University of medical sciences, Zand blvd

City
Shiraz

Province
Fars

Postal code

Approval date
2020-05-05, 1399/02/16

Ethics committee reference number

IR.SUMS.REC.1399.238

Health conditions studied

1

Description of health condition studied
Wound cause by elective cesarean section

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Investigation of wound swelling

Timepoint
Before intervention, days 10, 7, 3 and 12

Method of measurement
See by a gynecologist

2

Description
Evaluation of Wound Ecchymosis

Timepoint
Before intervention, days 10, 7, 3 and 12

Method of measurement
See by a gynecologist

3

Description
Evaluation of Wound discharge

Timepoint
Before intervention, days 10, 7, 3 and 12

Method of measurement
See by a gynecologist

4

Description
Check the extent of the wound

Timepoint
Before intervention, days 10, 7, 3 and 12

Method of measurement
See by a gynecologist

5

Description
Evaluation of wound redness

Timepoint
Before intervention, days 10, 7, 3 and 12

Method of measurement
See by a gynecologist

Secondary outcomes

empty

Intervention groups

1

Description

Control group: placebo

Category

Placebo

2

Description

Intervention group: Get Probiotics lysate 1% Prepared on chitosan nanogel base twice daily for 12 Days

Category

Treatment - Drugs

3

Description

Intervention group: Get Chitosan nano-gel product without probiotic twice daily for 12 days

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Hazrat Zeinab hospital

Full name of responsible person

Navid Omidifar

Street address

Crossroads of Defaemoghaddas

City

Shiraz

Province

Fars

Postal code

7153813311

Phone

+98 71 3726 5443

Email

omidifarn@sums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Younes Ghasemi

Street address

Rokn Abad, Karafarin St

City

Shiraz

Province

Fars

Postal code

134814336

Phone

+98 71 3242 4127

Email

Ghasemiy@sums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Shiraz 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

Shiraz University of Medical Sciences

Full name of responsible person

Ahmad Gholami

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Medical Pharmacy

Street address

Rokn Abad, Karafarin St

City

Shiraz

Province

Fars

Postal code

713451583

Phone

+98-711-2425305 (214)

Email

gholami@sums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Ahmad Gholami

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

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gholami@sums.ac.ir

Person responsible for updating data

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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

Undecided - It is not yet known if there will be a plan to make this available