Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

The effect of Rosuvastatin on operative wounds

Protocol summary

Study aim

In this study, we aim to investigate the therapeutic effect of rosuvastatin at the narrowing time (primary wound healing) and epithelialization time (complete wound healing) of surgical wounds.

Design

A clinical trial with a control group, with parallel groups, double-blind, randomized (randomized block design) Patients were randomly divided into two groups, control group(placebo), intervention group (receiving Composition of Rosuvastatin 2% in .Carboxymethyl cellulose). each group consists of 41 patients

Settings and conduct

Patients referring to the surgical department of Shahid Beheshti Hospital in Qom were randomly divided into two groups, control (receiving placebo) and intervention (receiving the drug). Placebo and the drug are in tubes. the surgical ward nurse is the only one who is aware of tubes containings. The patient and the health care group are not aware of the contents of the tubes. The contents of the tube are used twice daily for 7 days on the wound of patients. The patient will be monitored daily by her/his physician and primary wound healing time, complete healing time (epithelization) and the amount of analgesic will be measured.

Participants/Inclusion and exclusion criteria

participants: Patients referred to the surgical department of Shahid Beheshti Hospital in Qom who undergo surgery. inclusion criteria: 1-wounds due to operative incision exclusion criteria: 1-age below 11 years old 2-malignant wound 3-traumatic wound 4-infectious and dirty wound 5-oral statin consumption 6-opioid addiction 8-comorbidity (uncontrolled diabetes mellitus, immunosuppression , cirrhosis, renal failure)

Intervention groups

Control group (receiving placebo - Carboxymethyl cellulose) Intervention group (receiving Rosuvastatin 2% in Carboxymethyl cellulose)

Main outcome variables

1. age 2. gender 3. analgesic usage 4. primary wound healing time 5. complete wound healing (epithelization)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20120118008769N2**
Registration date: **2019-11-02, 1398/08/11**
Registration timing: **prospective**

Last update: **2019-11-02, 1398/08/11**
Update count: **0**

Registration date

2019-11-02, 1398/08/11

Registrant information

Name

Seyed Jalal Eshagh Hosseini

Name of organization / entity

Qom University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

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j.hosseini@muq.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-11-22, 1398/09/01

Expected recruitment end date

2020-11-21, 1399/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
The effect of Rosuvastatin on operative wounds

Public title
The effect of Rosuvastatin on wound healing
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Wounds due to operative incision
Exclusion criteria:
Age below 11 years old Malignant wound Traumatic wound Infectious and dirty wound Oral statin consumption Opioid addiction Comorbidity (uncontrolled diabetes mellitus, immunosuppression , cirrhosis, renal failure)
Age
From **11 years** old
Gender
Both

Phase
0
Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser

Sample size
Target sample size: **41**
Randomization (investigator's opinion)
Randomized
Randomization description
Blast Accident, Random Unit: Individual,
Blinding (investigator's opinion)
Double blinded
Blinding description
After signing the consent, the patient entered the study. Patients and the physician were not aware of the contents of the tube used for the patient.
Placebo
Used
Assignment
Parallel
Other design features
Rosuvastatin 2% will be used in this study

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Qom University of Medical Sciences
Street address
Qom, Shahid Lavasani St
City
Qom
Province
Ghoum
Postal code
3713649373
Approval date
2019-06-11, 1398/03/21
Ethics committee reference number
IR.MUQ.REC.1398.036

Health conditions studied

1

Description of health condition studied
Operative wound
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
"primary wound healing period" "complete wound healing (epithelialization) period"
Timepoint
Measurements are taken daily from the start of the intervention.
Method of measurement
Using the definitions of the two variables above in the surgical references , it is measured qualitatively by the physician.

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Patients receiving composition of Rosuvastatin 2% in Carboxymethyl Cellulose
Category
Treatment - Drugs

2

Description
Control group: patients receiving Carboxymethyl Cellulose
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center

Shahid Beheshti hospital, Qom

Full name of responsible person
seied jalal eshagh hosseini

Street address
shahid Beheshti st.

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Shahidbeheshti@muq.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Ghoum University of Medical Sciences

Full name of responsible person
AliReza Koohpayee

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Web page address

Grant name

Grant code / Reference number

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

Title of funding source
Ghoum 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
Ghoum University of Medical Sciences

Full name of responsible person
seied jalal eshagh hosseini

Position
Assistant Professor

Latest degree
Subspecialist

Other areas of specialty/work
General Surgery

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Person responsible for updating data

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Position

student

Latest degree

Medical doctor

Other areas of specialty/work

General Practitioner

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

No more information

Study Protocol

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

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not 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