Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Jul 2026

Evaluation of therapeutic effects of topical atorvastatin in postoperative ulcers: A randomized triple-blind placebo-controlled trial

Protocol summary

Study aim
Comparison of the effect of simple topical and nano-local atorvastatin formulations on surgical laparotomy wound healing

Design
This triple-blind clinical trial randomized in phase 3 was performed with parallel groups of 60 patients (20 per group). The first group receiving atorvastatin nano-emulgel, the second group receiving simple atorvastatin emulgel, and the third group receiving placebo emulgel. Number randomization was performed using Random Allocation software using the permutation block method. Patients will receive the drug twice a day for fourteen days.

Settings and conduct
Surgery unit of Dr. Rahnemoon Hospital of Yazd

Participants/Inclusion and exclusion criteria
inclusion criteria: 1) Candidates for laparotomy surgery 2) Sufficient literacy to fill out a consent form, understand the study, use the drug, and report pain and possible side effects Exclusion criteria: 1) Pregnant and lactating women 2) Patients with any peripheral or central neuropathic pain 3) Patients with a history of alcohol abuse or opioid dependence 4) Patients with a history of psychosis 5) Patients with a history of inflammatory disease who cannot discontinue NSAIDs or analgesics. 6) Patients with oral atorvastatin

Intervention groups
Group 1: Patients treated with atorvastatin nano emulgel 1% The second group: patients treated with atorvastatin emulgel 1% Group 3: Patients treated with placebo

Main outcome variables
Redness Edema Ecchymosis Wound size Wound Secretion

General information

Reason for update
The need for some changes during the trial

Acronym

IRCT registration information
IRCT registration number: **IRCT20190810044500N3**
Registration date: **2020-04-10, 1399/01/22**
Registration timing: **registered_while_recruiting**

Last update: **2023-03-14, 1401/12/23**
Update count: **1**

Registration date
2020-04-10, 1399/01/22

Registrant information

Name
Fatemeh Saghafi

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-11-13, 1398/08/22

Expected recruitment end date
2020-07-22, 1399/05/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Evaluation of therapeutic effects of topical atorvastatin in postoperative ulcers: A randomized triple-blind placebo-controlled trial

Public title
Effect of atorvastatin on ulcer
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Candidates for laparotomy surgery over 18 years old Sufficient literacy to fill out a consent form, understand the study, use the drug, report pain and possible side effects
Exclusion criteria:
Pregnant and lactating women Patients with any peripheral or central neuropathic pain Patients with a history of psychosis Patients with a history of inflammatory disease who cannot discontinue NSAIDs or analgesics. Patients with oral atorvastatin
Age
From **18 years** old
Gender
Both

Phase
3
Groups that have been masked

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

Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
Number randomization was performed using Random Allocation software using permutation block method. The numbers are sorted into three blocks and assigned to the codes A, B and C. That the codes A, B, and C are unknown for the researcher.
Blinding (investigator's opinion)
Triple blinded
Blinding description
Blindness was performed on clinical caregivers, including physicians and nurses, as well as variables assessors and data analysts.In this case, the three drugs nano-emulsifiers of atorvastatin and simple emulsifiers of atorvastatin and placebo with the letters A, B and C are randomly named by another person and this person is not responsible in this study.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Faculty of Ethics of Medical Sciences - Shahid Sadoughi University of Medical Sciences
Street address
Shahid Sadoughi University of Medical Sciences,Shohaday gomnam Blvd,Yazd
City
Yazd
Province
Yazd
Postal code
8915173143
Approval date
2019-11-03, 1398/08/12
Ethics committee reference number
IR.SSU.MEDICINE.REC.1398.196

Health conditions studied

1

Description of health condition studied
Post-operative wounds
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Redness
Timepoint
Before the start of the intervention - The first day -The seventh day -The fourteenth day
Method of measurement
Redness, Oedema, Ecchymosis, Discharge, Approximation (REEDA) scale

2

Description
Oedema
Timepoint
Before the start of the intervention - The first day -The seventh day -The fourteenth day
Method of measurement
REEDA Scale

3

Description
Ecchymosis
Timepoint
Before the start of the intervention - The first day -The seventh day -The fourteenth day
Method of measurement
REEDA Scale

4

Description
Wound Secretion
Timepoint
Before the start of the intervention - The first day -The seventh day -The fourteenth day
Method of measurement
REEDA Scale

5

Description
Approximation
Timepoint
Before the start of the intervention - The first day -The seventh day -The fourteenth day
Method of measurement
REEDA Scale

Secondary outcomes

1

Description
Quality of Life
Timepoint
On days 1, 7 and 14
Method of measurement
According to the Quality of Life Questionnaire of the European Organization for Research and Treatment of Cancer (EORTC QLQ-C30 (version 3)

2

Description
visual analog scale (VAS)
Timepoint
baseline, days 1, 2, , and 14
Method of measurement
The VAS consists of a 10cm line, with two end points representing 0 ('no pain') and 10 ('pain as bad as it could possibly be')

3

Description
unexpected adverse effects
Timepoint
At the end of the study
Method of measurement
Examining and asking the patient

Intervention groups

1

Description
Intervention group: Atorvastatin Emulgel
Category
Treatment - Drugs

2

Description
Control group: Placebo Emulgel
Category
Placebo

3

Description
Intervention group: Atorvastatin Nano-Emulgel
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahid Rahnemon Hospital
Full name of responsible person
Javad Zarekamali
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Alley 20,Pasdaran Blvd,Yazd
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Yazd 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?
No

Title of funding source
Shahid Sadoughi University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Private
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
Yazd University of Medical Sciences
Full name of responsible person
Fatemeh Saghafi
Position
Associate professor
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Medical Pharmacy
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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