Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Comparison between knife and electrocautery incisions in extremity's surgery

Protocol summary

Study aim

1. Comparison of surgical knife incision wound with electrocautery in operated patients 2. Determining the amount of postoperative pain in surgical incision with a scalpel 3. Determining the amount of postoperative pain in surgical incision with electrocautery 4. Determining the healing time of the surgical scar after surgical incision with a scalpel 5. Determining the healing time of the surgical scar after surgical incision with an electrocautery 6. Determining the amount of bleeding following surgical incision with a scalpel 7. Determining the amount of bleeding following surgical incision with electrocautery 8. Determining the extent of infection after surgery with a scalpel 9. Determining the rate of infection after electrocautery surgery

Design

A clinical trial with 3 parallel groups to evaluate the results of randomized wound healing on 90 patients. R software was used for randomization. The R Project for Statistical Computing https://www.r-project.org/

Settings and conduct

This study will be performed in Taleghani Hospital. Patients will be randomly divided into three equal groups. In one group, patients will be operated on with a knife, in the second group with an electrocautery and in the third group with a combined incision of a knife and an electrocautery. Wound complications will be evaluated at postoperative visits

Participants/Inclusion and exclusion criteria

Patients older than 18 years with a fracture who have the ability to follow up and evaluate the results for at least a specified period of time.

Intervention groups

1- Knife group 2- Electrocauter group 3- Combination therapy group of knife and electrocautery

Main outcome variables

1. Duration of surgical scar healing 2. The amount of bleeding following a surgical incision 3. The rate of infection after surgery

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180306038971N2**
Registration date: **2020-09-30, 1399/07/09**
Registration timing: **registered_while_recruiting**

Last update: **2020-09-30, 1399/07/09**
Update count: **0**

Registration date

2020-09-30, 1399/07/09

Registrant information

Name
Mohammad Ali Okhovatpour

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 21 2222 2222

Email address
okhovatpour@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-09-10, 1399/06/20

Expected recruitment end date

2020-10-11, 1399/07/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison between knife and electrocautery incisions in extremity's surgery

Public title
Comparison between knife and electrocautery incisions in extremity's surgery
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Patients who referred to orthopedic surgery in extremity's
Exclusion criteria:
Orthopedic surgery in extremities No blister necrosis infection and serious tissue damage at the incision site No active systemic infection No blood coagulation problems
Age
From **18 years** old to **60 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size
Target sample size: **90**
Randomization (investigator's opinion)
Randomized
Randomization description
The randomization for 3 intervention groups. The randomization method will done using software, 30 random numbers for each intervention group. The researcher can not play a role in predicting treatment of the disease, and choosing the type of treatment. random sequence will generate by software. Group 1: 30 Cases and Groups 2 :30 & 3: 30 cases. Software: random allocation website: https://random-allocation-software.software.informer.com/2.0/ Data: 90 codes for 90 patients (30 patients for each group)
Blinding (investigator's opinion)
Triple blinded
Blinding description
Patients have dressings to compare the results of each treatment after surgery and are evaluated by an orthopedist who has no knowledge of the treatment.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Medical Ethics and Law Research Center, Shahid Beheshti University of Medical Sciences, Tehran, Iran
Street address
Chamran highway, Yaman st, Arabi st, next to Taleghani hospital
City
Tehran
Province
Tehran
Postal code
1985717434
Approval date
2017-11-27, 1396/09/06
Ethics committee reference number
IR.SBMU.RETECH.REC.1396.419

Health conditions studied

1

Description of health condition studied
Wound complications due to surgical incision
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Bleeding during surgery
Timepoint
After 24 hours, 1 weeks, 2 weeks and 4 weeks
Method of measurement
Questionnaire

Secondary outcomes

1

Description
Infection
Timepoint
After 24 hours, 1 weeks, 2 weeks and 4 weeks
Method of measurement
Wound examination

2

Description
Surgical scar
Timepoint
After surgery
Method of measurement
Surgical ruler

Intervention groups

1

Description
Patients who are cut with a knife
Category
Treatment - Surgery

2

Description
Patients undergoing electrocautery incision
Category
Treatment - Surgery

3

Description
Patients undergoing knife and electrocautery incision
Category
Treatment - Surgery

Recruitment centers

1

Recruitment center
Name of recruitment center
بیمارستان آیت الله طالقانی
Full name of responsible person
محمد علی اخوت پور
Street address
Next to Shahid Beheshti University of Medical Sciences, Yemen St., Arabi St., Chamran highway.
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okhovatpour@sbmu.ac.ir
Web page address
https://taleghani.sbmu.ac.ir/

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
معاونت تحقیقات و فناوری دانشگاه علوم پزشکی شهید بهشتی
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Shahid Beheshti University of Medical Sciences, Yemen St., Arabi St., Chamran highway.
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Mpajouhesh@sbmu.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Shahid Beheshti 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
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Mohammad Ali Okhovatpour
Position
استادیار
Latest degree
Subspecialist
Other areas of specialty/work
Orthopedics
Street address
Taleghani hospital, next to Shahid Beheshti University of Medical Sciences, Yemen St., Arabi St., Chamran Highway
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okhovatpour@sbmu.ac.ir

Person responsible for scientific

inquiries

Contact

Name of organization / entity
Shahid Beheshti University of Medical Sciences

Full name of responsible person
Mohammad Ali Okhovatpour

Position
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Person responsible for updating data

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Assistant professor

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Subspecialist

Other areas of specialty/work
Orthopedics

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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
No - There is not 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
Yes - There is 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

Title and more details about the data/document
All data can be shared potentially after patients became unrecognizable.

When the data will become available and for how long
After completing the results and analyzing the data, access to them is allowed.

To whom data/document is available
This is only available for people working in academic institutions

Under which criteria data/document could be used
After obtaining written permission, the use of the data is permitted with reference to the source.

From where data/document is obtainable
Orthopedic ward in Taleghani hospital, next to Shahid Beheshti University of Medical Sciences, Yemen St., Arabi St., Chamran Highway. Tell: 00982123031216 Mohammad Ali Okhovat Pour Tell:00982123031294 e-mail: okhovatpour@gmail.com Yaser Safaei Tell:00989155113937 e-mail: yasersafa@yahoo.com

What processes are involved for a request to access data/document
After completing the results and analyzing the data, the use of the data is allowed after the written request.

Comments