

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 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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Tehran

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1985711151

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+98 21 2303 1294

Fax

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Email

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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Tehran

Postal code

1985717443

Phone

+98 21 2243 9781

Fax

+98 21 2243 9781

Email

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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1985711151

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+98 21 2303 1294

Email

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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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

Person responsible for updating data

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Mohammad Ali Okhovatpour

Position

Assistant professor

Latest degree

Subspecialist

Other areas of specialty/work

Orthopedics

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