Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

comparative study of the outcome of scalpel and electrosurgical technique for anterior abdominal wall incision in cesarean section

Protocol summary

Study aim

Comparison of the consequences of using scalpel and electrosurgery to cut the anterior abdominal wall during cesarean section

Design

Ŝingle blind clinical trials involving 88 participants with control groups and parallel groups, which will be randomly divided into two groups. The permutation block randomization method will be used for randomization.

Settings and conduct

This single blind study will be performed in the operating room of Allameh Behlool Hospital in Gonabad on women candidates for cesarean section, and the participants will be divided into two groups, one in the surgical incision group with scalpel and the other group with electrosurgery. The study is double-blind. Participants are unaware of what is being done to them, and the analyzer is unaware of the approach taken by each group. The permutation block randomization method will be used for randomization.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Women candidates for non-emergency cesarean section, age range 18 to 45 years, 37 to 41 weeks of gestation. Exclusion criteria:Participants should not have underlying disease, cardiopulmonary disease, skin disease, kidney failure, or immunodeficiency. If the person is addicted and sensitive to antibiotics, people who have taken anticoagulants should not be included in the study.

Intervention groups

Intervention group: includes people in whom abdominal incisions will be made using electrosurgery. control group: Includes people in whom abdominal incisions will be made using scalpel.

Main outcome variables

Bleeding; patient's hemodynamic status; duration of surgery

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200501047254N1**
Registration date: **2020-05-21, 1399/03/01**
Registration timing: **registered_while_recruiting**

Last update: **2020-05-21, 1399/03/01**
Update count: **0**

Registration date

2020-05-21, 1399/03/01

Registrant information

Name

Fatemeh Pouladkhay

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 5722 3360

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-05-09, 1399/02/20

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

comparative study of the outcome of scalpel and electrosurgical technique for anterior abdominal wall incision in cesarean section

Public title
comparative study of scalpel and electrosurgical technique for incision in cesarean section
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Cesarean section surgery Patients age (18-45 years) Pregnancy age 37 to 41 weeks Pfannestiel skin incision Satisfaction of participating in the project
Exclusion criteria:
Emergency cesarean section Vertical skin incisions Patients with incomplete records Patient addiction Chronic skin diseases such as psoriasis and eczema Antibiotic-sensitive patients Patients receiving anticoagulants Patients with heart and lung problems Underlying diseases such as diabetes, high blood pressure, liver disease, chronic anemia, kidney failure and immunodeficiency
Age
From **18 years** old to **45 years** old
Gender
Female

Phase
N/A
Groups that have been masked

- Participant
- Data analyser

Sample size
Target sample size: **88**
Randomization (investigator's opinion)
Randomized
Randomization description
It will be used to allocate groups through permutation block randomization. Patients participating in the study will be divided into two groups of 44 people using 4 blocks using letters A and B (for group equality). For permutation block randomization, the sealed envelope method will be used at random.
Blinding (investigator's opinion)
Double blinded
Blinding description
Blinding is such that the participant does not know what kind of actions will be taken for him; The analyst is also unaware of what is being done in each group. But since the measurement of the parameters is done by the researcher, the researcher will not be the blinding.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Mazandaran University of Medical Sciences
Street address
Sari, Farahabad Road,Mazandaran University of Medical Sciences, School of Paramedical Sciences
City
Sari
Province
Mazandaran
Postal code
۴۸۱۵۷۳۳۹۷۱
Approval date
2020-05-04, 1399/02/15
Ethics committee reference number
IR.MAZUMS.REC.1399.135

Health conditions studied

1

Description of health condition studied
cesarean section
ICD-10 code
O75.82
ICD-10 code description
Onset (spontaneous) of labor after 37 completed weeks of gestation but before 39 completed weeks gestation, with delivery by (planned) cesarean section

Primary outcomes

1

Description
Bleeding during surgery
Timepoint
Bleeding is measured during surgery.
Method of measurement
The amount of bleeding will be calculated by measuring the weight difference between dry and wet swabs.

2

Description
The patient's hemodynamic status includes heart rate and blood pressure
Timepoint
Before and after surgical incision
Method of measurement
The patient's heart rate is recorded from an anesthesia monitor and blood pressure is measured using a manometer

3

Description

Duration of surgery

Timepoint

From the beginning to the end of the surgery

Method of measurement

Using a timer

4

Description

Surgical incision time

Timepoint

From the moment of surgical incision to the end of incision and reaching the uterus

Method of measurement

Using a timer

5

Description

Baby's Apgar

Timepoint

1 and 5 minutes after birth

Method of measurement

observation

Secondary outcomes

1

Description

Patient pain after surgery

Timepoint

1, 4, 8, 16 and 24 hours after surgery

Method of measurement

Numerical Pain Rating Scale

2

Description

Hospital costs

Timepoint

After surgery

Method of measurement

Record the number of disposable items used during the operation, including yarns, cutter plates, cutter pens, the number of gases used, and total costs using the hospital's information system.

Intervention groups

1

Description

Intervention group: Surgical incision with electrosurgery

Category

Treatment - Surgery

2

Description

Control group: Surgical incision with Ṡcalpel

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Allameh Behlool Gonabadi Hospital

Full name of responsible person

Azam Sadat Mahmoudian

Street address

Saadi St., Vahdat Blvd., Allameh Behlool Gonabadi Hospital

City

Gonabad

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mazandaran University of Medical Sciences

Full name of responsible person

Dr. Majid Saeedi

Street address

Sari, Imam Square, Joibar Three Ways, at the beginning of Valiasr Highway, Central Headquarters of Mazandaran University of Medical Sciences

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magsaeedi@yahoo.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Mazandaran 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

Mazandaran University of Medical Sciences

Full name of responsible person

Fatemeh Pouladkhay

Position

Master Student

Latest degree

Bachelor

Other areas of specialty/work

Surgical technology

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Person responsible for scientific inquiries

Contact

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Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

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Person responsible for updating data

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Latest degree

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Other areas of specialty/work

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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

Not applicable

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