

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Evaluation and comparison of repair time, amount of bleeding, and pain at the episiotomy site created with Episizer-60 type scissors in comparison with Mayo type scissors in primiparous pregnant women

Protocol summary

Study aim

This study was performed to compare episiotomy with Mayo scissors in comparison with EPISCISSORS 60.

Design

A clinical trial with the control group with parallel groups; Randomized; Phase 4 on 64 patients. A table of random numbers is used for randomization.

Settings and conduct

The clinical trial study was performed on 64 women with first delivery referred to Al-Zahra hospital in Isfahan and was randomly divided into two groups of 32 intervention and control. There is no blinding in this study.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Mothers aged 18-40 years; Normal delivery and first delivery. Non-inclusion criteria: the age is more than 41 years; Cesarean delivery; Multiparity; Obesity (BMI more than 30); Third trimester bleeding; Maternal diabetes; chronic diseases.

Intervention groups

In the intervention group, with the progression of labor pain and the identification of the baby's head during delivery, a gynecologist and obstetrician; With an episiotomy angle of 60 degrees and with the help of the model of Episissors - 60; Gives an episiotomy incision at the perineal site. In the control group, as the labor pain progressed and the baby's head became clear during delivery, the obstetrician and gynecologist make an episiotomy incision in the perineal area with the help of Mayo model scissors.

Main outcome variables

Pain at the episiotomy site, Episiotomy incision repair time; the time of incision repair; the amount of bleeding until the incision is repaired.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20160521027998N8**

Registration date: **2021-04-13, 1400/01/24**

Registration timing: **prospective**

Last update: **2021-04-13, 1400/01/24**

Update count: **0**

Registration date

2021-04-13, 1400/01/24

Registrant information

Name

Maryam Hajhashemi

Name of organization / entity

Isfahan University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-04-15, 1400/01/26

Expected recruitment end date

2022-03-11, 1400/12/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation and comparison of repair time, amount of bleeding, and pain at the episiotomy site created with Episizer-60 type scissors in comparison with Mayo type scissors in primiparous pregnant women

Public title
Comparison of perineal incision (episiotomy) in using two different types of scissors.

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Being at the age of 18-40 years old Normal delivery The first delivery
Exclusion criteria:
Multiparity Obesity (BMI more than 30) Bleeding in third trimester Chronic diseases of the mother

Age
From **18 years** old to **40 years** old

Gender
Female

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **64**

Randomization (investigator's opinion)
Randomized

Randomization description
The random method is simple and a randomization tool is a random numbers table that the researcher considers to read the numbers from top to bottom in which the even numbers are for intervention A and the odd numbers for intervention B or the control group.

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Isfahan University of Medical Sciences

Street address

School of Medicine, Isfahan University of Medical Sciences and Health Services, Hezar Jerib St.

City

Isfahan

Province

Isfahan
Postal code
8174673461
Approval date
2020-03-11, 1398/12/21
Ethics committee reference number
IR.MUI.MED.REC.1399.796

Health conditions studied

1

Description of health condition studied

Episiotomy

ICD-10 code

O70

ICD-10 code description

Perineal laceration during delivery

Primary outcomes

1

Description

Time required to suture the episiotomy site

Timepoint

During episiotomy repair

Method of measurement

Timer (minutes)

2

Description

Pain at the episiotomy site

Timepoint

The day after delivery

Method of measurement

According to the pain questionnaire

3

Description

Time to repair the episiotomy incision

Timepoint

Two weeks after delivery

Method of measurement

Examination by a specialist and asking from the patient

4

Description

The amount of bleeding until suturing episiotomy site

Timepoint

Immediately after perineal incision and until the end of perineal repair time

Method of measurement

Number of used 5 * 5 cm pads

Secondary outcomes

1

Description

Pain during intercourse (dyspareunia)

Timepoint

Three months after delivery

Method of measurement

Asking from participants

Intervention groups

1

Description

Intervention group: in this group with the progression of labor pain and the identification of the baby's head during labor, a gynecologist and obstetrician, with an episiotomy angle of 60 degrees and with the help of scissors - 60, Gives an episiotomy incision at the perineum.

Category

Treatment - Other

2

Description

Control group: in this group, with the progression of labor pain and the identification of the baby's head during delivery, a gynecologist and obstetrician with the help of Mayo model scissors; Gives an episiotomy incision at the perineal site.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Al-Zahra hospital in Isfahan

Full name of responsible person

Maryam Haji Hashashemi

Street address

Al-Zahra Educational and Medical Center ,Safa boulevard

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Dr.Mojgan Mortazavi

Street address

Isfahan University of Medical Sciences and Health Services, Hezar Jerib street

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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

Vice Chancellor for Research, Isfahan 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

Esfahan University of Medical Sciences

Full name of responsible person

Farnaz Sattary Aberoo

Position

Resident of Obstetrics and Gynecology

Latest degree

Medical doctor

Other areas of specialty/work

Gynecology and Obstetrics

Street address

School of Medicine; Isfahan University of Medical Sciences and Health Services; Hezar Jerib street

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Maryam Haji Hashemi

Position

Assistant professor

Latest degree

Subspecialist

Other areas of specialty/work

Gynecology and Obstetrics

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Person responsible for updating data

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Name of organization / entity

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Position

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Latest degree

Subspecialist

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

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