

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Jun 2026

Comparison of the length of perineal laceration in primiparous women with and without episiotomy, Shabikhani hospital in Kashan

Protocol summary

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Summary

This study was carried out to compare the length of perineal laceration in primiparous women with and without episiotomy referred to Shabikhani hospital in Kashan in 2006-2007. This clinical trial study carried out on 180 primiparous women at term and single fetus with cephalic presentation and estimated fetal weight of 2500-3500 grams. The participants were assigned randomly and equally into intervention and control groups. Delivery carried out without episiotomy in intervention group but with episiotomy in control group. The length of posterior perineal laceration, anterior perineal laceration and need for repair were compared between groups.

Recruitment status

Recruitment complete

Funding source

Vice-chancellor for Research, Kashan University of Medical Sciences

Expected recruitment start date

2006-11-11, 1385/08/20

Expected recruitment end date

2007-08-21, 1386/05/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138809182699N2**

Registration date: **2010-03-06, 1388/12/15**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2010-03-06, 1388/12/15

Registrant information

Name

Farzaneh Saberi

Name of organization / entity

Kashan University Of Medical Sciences

Country

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Phone

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Email address

Scientific title

Comparison of the length of perineal laceration in primiparous women with and without episiotomy, Shabikhani hospital in Kashan

Public title

Comparison of the length of perineal laceration in primiparous women with and without episiotomy, Shabikhani hospital in Kashan

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: primiparous, term pregnancy, single fetus, cephalic presentation, estimated fetal weight of 2500-3500 grams. Excluding criteria: multiple pregnancy, forceps and vacuum delivery, estimated fetal weight lower than 2500 or upper than 3500 gram, preterm labor, fetal malpresentation, occiput posterior position, precipitated labor and all complications that need to decrease length of second stage of labor (such as fetal distress, hemorrhage ...)

Age

From **15 years** old to **45 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size:

Randomization (investigator's opinion)

Randomized

Randomization description**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**

Kashan University Of Medical Sciences

Street address

Kashan University Of Medical Sciences, Ghotb-e-Ravandi Blvd.,

City

Kashan

Postal code

8715981151

Approval date

empty

Ethics committee reference number

3260/1/5/29/پ

Health conditions studied**1****Description of health condition studied**

Delivery with episiotomy

ICD-10 code

O80.0

ICD-10 code description

Spontaneous vertex delivery

Primary outcomes**1****Description**

Length of perineal laceration

Timepoint

Immediately post partum

Method of measurement

Standard ruler

Secondary outcomes**1****Description**

post partum hemorrhage

Timepoint

During first hour after delivery

Method of measurement

Observation

Intervention groups**1****Description**

Episiotomy

Category

Prevention

2**Description**

no episiotomy

Category

Other

Recruitment centers**1****Recruitment center****Name of recruitment center**

Kashan University of Medical Science

Full name of responsible person

Dr. Mansoureh Samimi

Street address**City**

Kashan

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Kashan University of Medical Sciences

Full name of responsible person

Gholamali Hamidi

Street address

Vice Chancellor for Research, Kashan University of Medical Sciences

City

Kashan

Grant name**Grant code / Reference number****Is the source of funding the same sponsor**

organization/entity?

Yes

Title of funding source

Kashan University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

empty

Person responsible for general inquiries**Contact****Name of organization / entity**

Kashan University of Medical Sciences

Full name of responsible person

Farzaneh Saberi

Position

MS. Faculty Member

Other areas of specialty/work**Street address**

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Web page address**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Kashan University of Medical Sciences

Full name of responsible person

Mansoureh Samimi

Position

Gynecologist

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Web page address**Person responsible for updating data****Contact****Sharing plan****Deidentified Individual Participant Data Set (IPD)**

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty