

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Aug 2026

The effect of Perineal Massage in pregnancy period on the rate of Perineal episiotomy and rupture

Protocol summary

Summary

Purpose : This study aims to determine the effect of Prineal massage in pregnancy women on the rate of Perineal episiotomy rupture and a single-blinded has been done randomly . The survey population : It involved all of the pregnant women waiting for a normal labor referred to the clinics for examination . Entry and exit criteria : The age of a 36- weeks conception or more was Nulliparos . Doing Kegel's exercises or the other exercises as professional and the lack of mother's cooperation during the study were regarded as the exit criteria .I Sample size : 100 pregnant women were selected using simple sampling and placed into two 50 - person groups of intervention and control . Intervention : Perineal massage was initiated from 36 weeks of conception . 50 pregnant women referred to the clinics daily and Perineal massage done for them with a softer solution in water like coconut or olive oils for 3 - 10 min a day by expert midwives . Time : Perineal massage was done daily during 30 days . Initial outcome :At the end , the need to Perineal episiotomy and the rate of its rupture were compared in two groups .

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201202288069N2**
Registration date: **2012-03-19, 1390/12/29**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2012-03-19, 1390/12/29

Registrant information

Name

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Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Isfahan University of Medical Sciences

Expected recruitment start date

2011-12-22, 1390/10/01

Expected recruitment end date

2012-05-28, 1391/03/08

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of Perineal Massage in pregnancy period on the rate of Perineal episiotomy and rupture

Public title

The effect of Perineal Massage on the Perineal rupture

Purpose

Prevention

Inclusion/Exclusion criteria

Entry criteria : The age of a 36- weeks conception or more was Nulliparos. exit criteria :Doing Kegel's exercises or the other exercises as professional and the lack of mother's cooperation during the study were regarded as the exit criteria .

Age

No age limit

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample sizeTarget sample size: **100****Randomization (investigator's opinion)**

Randomized

Randomization description**Blinding (investigator's opinion)**

Single blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Islamic Azad University of Najaf abad Branch

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Approval date

2010-09-10, 1389/06/19

Ethics committee reference number

51501851101002

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

pregnancy & delivery

ICD-10 code

o90

ICD-10 code description

Complications of the puerperium, not elsewhere classified

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

No episiotomy & perineal lacerations

Timepoint

delivery on time

Method of measurement

absservation & questioneir

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

Pain and vaginal bleeding

Timepoint

Postpartum of daily

Method of measurement

Observation and Examination

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

50 pregnant women referred to the clinics daily and Perineal massage done for them with a softer solution in water like coconut or olive oils for 3 – 10 min a day by expert midwives .

Category

Prevention

2**Description**

Control group: no effort was made to them.

Category

Prevention

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

Shariati hospital

Full name of responsible person

Azam Foroghpour

Street address

Shariati hospital, Shariati Street

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

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Full name of responsible person

Dr Reza Ebrahimi (Research Assistant)

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Grant name

Grant code / Reference number

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

Title of funding source
Islamic Azad University of Najafabad

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
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Full name of responsible person
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Position
Master of midwifery

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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