Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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 .l 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 episiotory 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

Fatemeh Salmani

Name of organization / entity

Esfahan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 31 1581 2914

Email address

f-salmani@iaun.ac.ir

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 size
Target 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 Universityof Najaf abad Branch
Street address
Islamic Azad Universityof Najaf abad Branch, Najaf abad
City
Esfahan
Postal code
517
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
abservation & 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 Foroghipour
Street address
Shariati hospital, Shariati Street
City
Esfahan

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Islamic Azad University of Najafabab
Full name of responsible person
Dr Reza Ebrahimi(Research Assistant)
Street address
Islamic Azad University of Najaf abab Branch, University Street, Najaf bad

City
Esfahan
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 Najafabab
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
Islamic Azad University of Najaf abad Branch
Full name of responsible person
Azam Foroghipour
Position
Master of midwifery
Other areas of specialty/work
Street address
Midwifery group,Islamic Azad University of Najaf abad Branch, Najaf abad
City
Esfahan
Postal code
517
Phone
+98 33 1229 1111
Fax
Email
azamforoghipour@yahoo.com
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
Islamic Azad University of Najaf abad Branch
Full name of responsible person
Azam Foroghipour
Position
Master of midwifery
Other areas of specialty/work
Street address
Midwifery group, Islamic Azad University of Najaf abad Branch
City
Esfahan
Postal code
517
Phone
+98 33 1229 1111
Fax
Email
azamforoghipour@yahoo.com
Web page address

Person responsible for updating data

Contact
Name of organization / entity
Islamic Azad University of Najaf abad Branch
Full name of responsible person
Fatemeh Salmani
Position
Master of nursing
Other areas of specialty/work
Street address
Nursing group, Islamic Azad University of Najaf abad Branch, Najaf abad
City
Esfahan
Postal code
8199855781
Phone
+98 33 1229 1111
Fax
Email
f-salmani@iaun.ac.ir ft_salmani@yahoo.com.au
Web page address

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