

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Jul 2026

Effect of pushing with breathing techniques on perineal status and delivery outcome in nulliparous in Kamali hospital in Karaj

Protocol summary

Summary

This study is a randomized controlled clinical trial that was done in Kamali hospital in Karaj with the participation of 166 nulliparous women in 40-37 weeks of pregnancy who were candidates for vaginal delivery. The samples were randomly divided into two groups, using breathing techniques and routine maneuver (Valsalva maneuver). In control group pushing was done with keeping breath. In the breathing technique The mother was asked with the onset of abdominal pain to inhale two deep abdominal breaths and then exhale with open mouth. During controlled exhale ,they are asked to push for 5-4 seconds and then start the next push again according to the training instruction. In intervention group, pushing continued until crowning stage. After that, mothers were asked to control pushing by using blowing technique until ejection of the neonate head occurred .this process must be carry out only with uterine contractions, without increased abdominal pressure caused by moms excessive pushing. IN routine group, Valsalva maneuver continue until fetal scalp got out. Outcomes of this study include perineal status check, length of second stage of labor, fetal heart condition and the Apgar score.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014092819310N1**
Registration date: **2014-10-18, 1393/07/26**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2014-10-18, 1393/07/26

Registrant information

Name

Zohre Ahmadi

Name of organization / entity

Sadughi University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Shahid Beheshti University of Medical Sciences

Expected recruitment start date

2014-09-19, 1393/06/28

Expected recruitment end date

2014-12-22, 1393/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of pushing with breathing techniques on perineal status and delivery outcome in nulliparous in Kamali hospital in Karaj

Public title

Effect of pushing with breathing techniques on perineal status and delivery outcome in nulliparous in Kamali hospital in Karaj

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria : age 18-35; gestational age ≥ 37 weeks ; Were anticipating a vaginal birth (both normal

spontaneous or instrumental) ;normal BMI ;having 6 score or more in vaginal exam according to Brinks score
Exclusion criteria :Did not wish to participate ;Had an epidural analgesia ;emergency Cesarean ;fetal birth weight> 3999 gr or<2500 ; head circumference <32cm or>38cm

Age

From **18 years** old to **35 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **166**

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

Ethics committee of Shahid Beheshti university

Street address

Nursing Midwifery Collage; Niayes; Valiaasr AV;
Tehran

City

Tehran

Postal code

1985717443

Approval date

2013-09-14, 1392/06/23

Ethics committee reference number

400/4013

Health conditions studied

1

Description of health condition studied

delivery

ICD-10 code

O80.0

ICD-10 code description

Spontaneous vertex delivery

Primary outcomes

1

Description

perineal outcome

Timepoint

as soon as ending delivery

Method of measurement

according to definition of perineal damage

2

Description

apgar

Timepoint

as soon as ending of delivery

Method of measurement

according to apgar definition

3

Description

length of second stage of labor

Timepoint

at the end of intervention befor delivery

Method of measurement

hour(minute)

4

Description

abnormal FHR sound

Timepoint

during intervention every 5 minuts

Method of measurement

sony keyd

Secondary outcomes

empty

Intervention groups

1

Description

The intervention group used breathing techniques from completing dilatation until fetus exit this means that with every contraction every muscle in their body starting to relax, by breathing deeply through the nose and blowing abdomen simultaneously .then while the abdominal muscles are contracted, they carry out a deep breath through half open mouth or through nose .after that they take a deep breath again and expiration with all strength over half-open mouth during 5-4 seconds and then after re breathing ,the next force will be started until the contraction ends. At the end of the contraction, two deep abdominal breathing was done (with an open glottis). This trend continued until the head of neonate is going to exit. At this time people took a deep breath and start to blow for 3-2 seconds .

Category

Prevention

2

Description

In control subjects using Valsalva maneuver for pushing in the second stage. This means that initially took a deep breath and hold it for 10 seconds and proceed with straining to have a closed glottis

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Kamali hospital

Full name of responsible person

Mrs Tahlavi

Street address

Kamali AV, Karaj Alborz

City

Karaj

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for research of Shahid Beheshti University of Medical Sciences

Full name of responsible person

Ali Ziaee

Street address

MedicalCollage,Kudakyar AV,Evin,Tehran

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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

Vice Chancellor for research of Shahid Beheshti 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

Shahid Sadughi University of Medical Sciences

Full name of responsible person

Zohre Ahmadi

Position

Student Of 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