

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 in 1392 with the participation of 166 primiparous women 40-37 weeks who were candidates for vaginal birth. The samples were randomly divided into two groups, using breathing techniques and routine pushing (Valsalva maneuver) were used. In control group pushing was done with keeping breathing. In the breathing technique The mother was asked with the onset of abdominal pain do two deep breaths and then pulled another deep breath and exhale with open mouth and by controlling the exhale ,pushing during 5-4 seconds and then start the next pushing according to train. In intervention group, pushing continued until crowning . After that, mothers were directed to control pushing by using blowing breathing technique in order to expulsion of the head occurred 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: **IRCT201405258801N7**

Registration date: **2014-07-25, 1393/05/03**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2014-07-25, 1393/05/03

Registrant information

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Masoumeh Simbar

Name of organization / entity

Shahid Beheshti University for Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Shahid Beheshti University of Medical Sciences

Expected recruitment start date

2014-08-10, 1393/05/19

Expected recruitment end date

2014-12-03, 1393/09/12

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 cesarian ;occyput posteriol ;fetal birth weight> 3999 gr or<2500 ; head circumferencer <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)

Single blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Shahid Beheshti

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

accorging to apgar definition

3

Description

during second stage of labor

Timepoint

at the end of intervention befor delivery

Method of measurement

hour(minute)

4

Description

insterument delivery

Timepoint

after intervention

Method of measurement

have- not have

5

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, breathe deeply through the nose is pulled so that the abdomen to protrude forward and through the nose or mouth and then through the nose or mouth half open while the abdominal muscles are contracted to carry out

a deep breath through opening half .then take a deep breath again and pulled with all our strength, and with half-open mouth during 5-4 seconds and then empty air with a longer tail and did the next force until that contract ends.At the end of the contraction did other two the deep abdominal breathing (straining with an open glottis). This trend continued until the head is going to exit. At this time people took a deep breath and began to blowing as long as 3-2 seconds Such as blowing a few candles .

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

City

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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

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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

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**

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Full name of responsible person

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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