The effect of abdominal massage with breathing techniques in active phase on the resulting outcomes of labor in primiparous women

Protocol summary

Summary
This study was designed to investigate the effect of abdominal massage with breathing techniques in active phase on the resulting outcomes of labor in primiparous women referred to Lolagar Hospital in Tehran, Iran in 2010. In this study, 96 primiparous and healthy women own single alive fetus with gestational age between 37 and 42 weeks in onset active phase of labor allocated in three groups with systematic random allocations method. The first experimental group (n=32) received effleurage abdominal massage during onset 30 minutes of the active and transitional phases of labor. The second experimental group (n=32) received effleurage abdominal massage with Lamaze breathing techniques during onset 30 minutes of the active and transitional phases of labor. The control group (n=32), received routine cares of labor room without any intervention during of the two active and transitional phases. In each of three groups, pain severity of labor before and after intervention during both phases, duration of the first, second and third stages of delivery, type of delivery, the Apgar score of the first and fifth minutes of newborn and mother’s satisfaction after delivery were investigated by assistant researchers.

General information

Acronym
IRCT registration information
IRCT registration number: IRCT138807192248N4
Registration date: 2012-04-25, 1391/02/06
Registration timing: retrospective

Recruitment status
Recruitment complete
Funding source
Tehran University of Medical Sciences, Vice chancellor for research

Expected recruitment start date
2010-07-23, 1389/05/01
Expected recruitment end date
2010-12-21, 1389/09/30
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The effect of abdominal massage with breathing techniques in active phase on the resulting outcomes of labor in primiparous women

Public title
The effect of abdominal massage with breathing techniques on the resulting outcomes of labor in primiparous women

Purpose
Supportive

Inclusion/Exclusion criteria
Inclusion criteria: primiparous and Healthy women; single alive fetus; gestational age between 37 to 42 weeks, and augment healthy fetus by sonography. Exclusion criteria: all women that exit from normal labor procedure; unable to done breathing techniques correctly; labor induction or stimulation by oxytocin; tendency mother for exit from the research.

Age
No age limit

Gender
Female
Phase
N/A

Groups that have been masked
None

Sample size
Target sample size: 96

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
Tehran University of Medical Sciences
Street address
keshavarz Bul
City
Tehran
Postal code
19395/4798

Approval date
2010-07-19, 1389/04/28

Ethics committee reference number
1744284

Health conditions studied

1

Description of health condition studied
severity of labor pain and resulting outcomes of labor

ICD-10 code
000-099

ICD-10 code description
Pregnancy, childbirth and the puerperium

Primary outcomes

1

Description
severity of labor pain on active phase of labor

Timepoint
onset active phase and after 30 minutes

Method of measurement
Digital chronometer Germany

Secondary outcomes

1

Description
Satisfaction of intervention method

Timepoint
Before from mother discharging of hospital

Method of measurement
satisfaction questionnaire engender by researcher

2

Description
Apgar score of neonate

Timepoint
1 and 5 minutes after delivery

Method of measurement
Observation and record in questionnaire

3

Description
Type of delivery

Timepoint
After delivery of fetus
Method of measurement
Observation and record in questionnaire

Intervention groups

1
Description
Intervention 1: 30 minutes abdominal massage during uterine contractions on onset active and transitional phase of labor.
Category
Prevention

2
Description
Intervention 2: 30 minutes abdominal massage plus Lamaze breathing technique during uterine contractions on onset active and transitional phase of labor.
Category
Prevention

3
Description
Control group: Routine care on labor room
Category
N/A

Recruitment centers

1
Recruitment center
Name of recruitment center
Lolagar Hospital
Full name of responsible person
Arezow Haseli
Street address
Khosh Ave, Tehran
City
Tehran

Sponsors / Funding sources

1
Sponsor
Name of organization / entity
Tehran University of Medical Sciences, vice chancellor for research
Full name of responsible person
Dr. Akbar Fotuhi
Street address
Kgod Street, Keshavarz bul, Tehran
City
Tehran
Grant name
Grant code / Reference number
Is the source of funding the same sponsor
organization/entity?
Yes
Title of funding source
Tehran University of Medical Sciences, vice chancellor for research
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
Tehran University of Medical Sciences, School of Nursing and Midwifery
Full name of responsible person
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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