Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Title of proposal: comparison of delivery outcomes between 2 methods of physiologic and traditional delivery in women referred to norani shahid hospital in talesh in 2011-12

Protocol summary

Summary

A randomized, single-center, single blind study is conducted to compare outcomes of pregnancy in traditional and physiological methods. Physiological childbirth: according to the Country Guideline, it's a method of natural childbirth, and Treatment approaches to alleviate include Non-medical Pain relievers. Aromatherapy is a way in which you can rub lavender oil between your palms, and massage the parturient woman's waist and hips during all stages of labor ; she can use birth ball and there is no limitation during labor as well as she can freely choose any position ; serum and oxytocin is not injected her in routine way; oxytocin injection is based on partograph. Cardiac monitoring is not continuously; Episiotomy can be performed immediately if needed (according to method in proposal). Traditional childbirth: during the study, traditional childbirth is defined as: birth mother's hospitalization based on obstetric Indications, continuous fetal heart rate monitoring (FHM), amniotomy is not performed (unless placental abruption is suspected), oxytocin should not be used (unless partograph-based intervention is necessary), using serum and branol, episiotomy was definded for women having their first pregnancy . Inclusion criteria: women aged between 18-35 years; gestational age 37-42 weeks based on the first day of the last menstrual period or based on ultrasound in gestational age prior to12 weeks; singleton pregnancy with cephalic presentation; having low-risk pregnancy (absence of chronic illness like heart disease, hypertension, lung disease, diabetes, anemia, urinary tract infection (UTI), thyroid disease, Epilepsy, no spontaneous abortion, Bleeding or any abnormal cases; no specific or unauthorized drug is used during pregnancy; primiparous pregnancy; normal fetus-baby weigh less than 4000 grams by using Johnson's formula [W=(-N 155], fundal height (cm) above the pubic symphysis minus 12 if Vertex above Ischial Spine or minus 11 if below Ischial Spines; no history of infertility; normal pelvis diameters (based on vaginal examination),height should not be under 145cm; absence of mental illness or any other disorder that makes her unable to communicate(deafness – blindness) and interesting to participate in research study. Exclusion criteria are: maternal-fetal emergency intervention is required (Bleeding, like placental abruption, emergency cesarean for any reason) during labor and withdraw from the partnership. Primary outcomes: to compare the average length of the first stage of labor in physiological and traditional childbirth; to compare the average length of the second stage of labor in physiological and traditional childbirth; to compare the average length of the third stage of labor in physiological and traditional childbirth; to compare maternal outcomes (type of delivery -post partum infection); comparing neonatal outcomes(apgar score Neonatal APG, need to be Hospitalized in NICU)is related to The study population of pregnant women in Talesh –shahid noorani hospital)

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201110153027N15**
Registration date: **2011-10-27, 1390/08/05**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2011-10-27, 1390/08/05

Registrant information

Name

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Name of organization / entity
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Recruitment status
Recruitment complete
Funding source
Tabriz University of Medical Sciences

Expected recruitment start date
2011-10-23, 1390/08/01
Expected recruitment end date
2012-03-19, 1390/12/29
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Title of proposal: comparison of delivery outcomes between 2 methods of physiologic and traditional delivery in women referred to norani shahid hospital in talesh in 2011-12

Public title
comparison of delivery outcomes between 2 methods of physiologic and traditional delivery
Purpose
Other
Inclusion/Exclusion criteria
Inclusion criteria 1- Women aged between 18-35 years 2- Gestational age 37-42 weeks based on the first day of the last menstrual period or based on ultrasound in Gestational age prior to12 weeks. 3- singleton pregnancy with cephalic presentation 4- Having low-risk pregnancy (absence of chronic illness like heart disease, hypertension, lung disease, diabetes, anemia, urinary tract infection (UTI), thyroid disease, Epilepsy, no spontaneous abortion, Bleeding or any abnormal cases . 5- No specific or Unauthorized drug is used during pregnancy 6- primiparous pregnancy 7- normal fetus-baby weigh less than 4000 grams by using Johnson's formula [W=(-N 155], Fundal height (cm) above the pubic symphysis minus 12 if Vertex above Ischial Spine or minus 11 if below Ischial Spines. 8- no history of infertility 9- normal pelvis diameters (based on vaginal examination),height should not be under 145cm 10- absence of mental illness or any other disorder that makes her unable to communicate(deafness – blindness) 11- Interesting to participate in research study Exclusion criteria 1- maternal-fetal emergency intervention is required (Bleeding, like placental abruption, emergency cesarean for any reason) during labor 2- withdraw from the partnership
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:
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
Tabriz University of Medical Sciences
Street address
Tabriz University of Medical Sciences, 2 central Research Organization
City
Tabriz
Postal code
347-51745
Approval date
2011-10-11, 1390/07/19
Ethics committee reference number
9032

Health conditions studied

1

Description of health condition studied
Delivery
ICD-10 code
O80
ICD-10 code description
Single spontaneous delivery

Primary outcomes

1

Description
Neonatal outcomes: Apgar scor
Timepoint

After intervention

Method of measurement

Cheklist/ examination/ observation

2

Description

Neonatal outcomes:ABG

Timepoint

After intervention

Method of measurement

Cheklist/ examination/ observation

3

Description

Neonatal outcomes: NICU

Timepoint

After intrevention

Method of measurement

Cheklist/ examination/ observation

4

Description

Maternal outcomes: Post partum infection

Timepoint

After intervention

Method of measurement

Cheklist/ examination/ observation

5

Description

Average lenghth of the second Stage of labor

Timepoint

Lenghth of intervention

Method of measurement

Partograph

6

Description

Average lenghth of the third stage of labor

Timepoint

Lenghth of intervention

Method of measurement

Partograph

7

Description

Maternal outcomes: Type of delivery

Timepoint

One month after intervention

Method of measurement

Cheklist/ examination/ observation

8

Description

Average lenghth of the first stage of labor

Timepoint

Lenghth of intervention

Method of measurement

Partograph

Secondary outcomes

empty

Intervention groups

1

Description

Physiological childbirth: according to the Country Guideline, it’s a method of natural childbirth, and Treatment approaches to alleviate include Non-medical Pain relievers: Aromatherapy is a way in which You can rub lavender oil between your palms , and massage the parturient woman’s waist and hips during all stages of labor ; she can use birth ball and there is no limitation during labor as well as she can freely choose any position ; serum and oxytocin is not injected her in routine way; oxytocin injection is based on partograph. cardiac monitoring is not continuously; Episiotomy can be performed immediately if needed(according to method in proposal).it is notable that if it is necessary , I will be trained by an expert instructor who helps me getting my Birth certificate.

Category

Other

2

Description

Traditional childbirth: During the study, traditional childbirth is defined as : birth mother's hospitalization based on Obstetric Indications, continuous fetal heart rate monitoring(FHR), amniotomy is not performed (unless placental abruption is suspected), oxytocin should not be used (unless partograph-based intervention is necessary),using serum and branol, episiotomy was definded for women having their first pregnancy .it It should be noted that in traditional childbirth Everything is consistent with what is being done in the country.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Norani SHahid Hospital in Talesh

Full name of responsible person

Samiyeh Kazemi

Street address

Gillan,Talesh,SHahid Beheshti Ave.Norani SHahid Hospital

City

Ramsar

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tabriz University of Medical Sciences, Department Scholarships
Full name of responsible person
Department Scholarships
Street address
Tabriz, Department Scholarships
City
Tabriz
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Tabriz University of Medical Sciences, Department Scholarships
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

Person responsible for scientific inquiries

Contact
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Full name of responsible person
Fahimeh Shafaie
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Person responsible for updating data

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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