

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Jun 2026

the effect of spouse attendance in the labor on father's role adaptation and active phase duration

Protocol summary

Study aim

The effect of husbands' attendance in the labor on adaptation to father's role

Design

In this study, available sampling will be selected from the clients of Rasoul Akram maternity hospital in Kalaleh. In such a way that the clients of Kalaleh maternity hospital will be examined during the days of the week from Saturday to Thursday if they wish to participate in the study. The clients should consider even days for the intervention group (A) and odd days for the control group (B).

Settings and conduct

Sampling will be selected from those referred to Rasoul Akram Hospital maternity hospital in Kalaleh. The clients of Kalaleh maternity hospital will be examined during the days of the week from Saturday to Thursday if they wish to participate in the study, so that the clients have even days for the intervention group (A) and odd days for the control group (B). Will be considered

Participants/Inclusion and exclusion criteria

Iranian citizenship Ability to understand and speak, read and write in Persian Fetal health based on ultrasound and pregnancy tests The mother must have a normal delivery. Gestational age is 38-42 weeks of single pregnancy and live fetus. Becoming a father for the first time Wanted pregnancy The father should be with his wife for at least 2 hours during labor Exclusion criteria: Withdrawal from continuing to participate in the study Early cesarean section after entering labor

Intervention groups

fathers who for their wife's childbirth with 38-42 weeks gestational age and have normal delivery conditions will refer to Kalaleh Hospital and wish to be with their spouse for at least 2 hours as a active phase

Main outcome variables

Determining the percentage of compliance with the paternal role in cases of presence or absence of the spouse during labor, Active phase duration

General information

Reason for update

Adding the active phase duration to intervention outcomes

Acronym

IRCT registration information

IRCT registration number: **IRCT20180408039229N2**

Registration date: **2021-03-23, 1400/01/03**

Registration timing: **registered_while_recruiting**

Last update: **2022-09-13, 1401/06/22**

Update count: **1**

Registration date

2021-03-23, 1400/01/03

Registrant information

Name

Narjes Sadat Borghei

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 17 3254 9718

Email address

dr.borghei@goums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-11-21, 1399/09/01

Expected recruitment end date

2021-06-20, 1400/03/30

Actual recruitment start date

2020-11-16, 1399/08/26

Actual recruitment end date

2021-05-20, 1400/02/30

Trial completion date

2021-07-21, 1400/04/30

Scientific title

the effect of spouse attendance in the labor on father's role adaptation and active phase duration

Public title

The effect of spouse attendance in the labor on father's role adaptation and active phase duration

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

Married men, living in Kalaleh, Iranian citizenship, Ability to understand and speak, read and write in Persian, Experience becoming a father for the first time, Their wife's have normal vaginal delivery condition with GA 38-42 weeks, Presence behind her wife for at least 2 hours during labor, Hospitalization at the onset of active phase of labor

Exclusion criteria:

Withdrawal of the spouse from participating in the prenatal study Early cesarean section after entering labor

Age

No age limit

Gender

Male

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **58**

Actual sample size reached: **57**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization Method: block Randomization Random unit: Individual For random assignment of samples to the intervention and control groups, the quadratic block method with permutations (AABB-ABAB-ABBA-BABA-BAAB-BBAA) will be used. A represents the intervention group and B represents the control group. The blocks are randomly selected without placement and the samples will be assigned to groups according to their permutations.

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 Golestan University of Medical Sciences

Street address

Research Deputy of Golestan University of Medical Sciences, Beginning of the Road of Shasta Kalateh., 5th Km of Gorgan Kurdkuy Road

City

Gorgan

Province

Golestan

Postal code

4934174515

Approval date

2020-10-18, 1399/07/27

Ethics committee reference number

IR.GOUMS.REC.1399.231

Health conditions studied**1****Description of health condition studied**

husbands' attendance in the labor

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

Husbands' adaptation to father's role

Timepoint

Two month after delivery

Method of measurement

Father's role adaptation questionnaire

2**Description**

active phase duration

Timepoint

From the beginning of hospitalization in the active phase of labor every one hour until delivery

Method of measurement

Partograph form

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: the presence of the husband will be require for at least two hours during active phase of

labor.
Category
Behavior

2

Description

Control group: will not receive any intervention.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Kalaleh hospital

Full name of responsible person

Nahid Haji Hosseini

Street address

Al-Ghadir Square

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4991844494

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nahidhaji59@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Gorgan University of Medical Sciences

Full name of responsible person

Honarvar, Mohammad Reza

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Sayyad Shirazi Blvd.

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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

Gorgan University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Gorgan University of Medical Sciences

Full name of responsible person

Narjes Sadat Borghei

Position

Assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Midwifery

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Person responsible for updating data

Contact

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Not applicable

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

Data from the intervention and control groups can be published up to six months after the publication of the article

When the data will become available and for how long

Up to six months after the publication of the article

To whom data/document is available

Researchers who request in writing from the correspondence author

Under which criteria data/document could be used

systematic review

From where data/document is obtainable

correspondence author

What processes are involved for a request to access data/document

Send a written request to the email of the correspondence author up to six months after the publication of the article

Comments