

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 May 2026

The effect of vitamin D intake in the mother during childbirth on the incidence of nonspecific respiratory distress

Protocol summary

Registration timing: **registered_while_recruiting**

Study aim

Determining the effect of vitamin D administration on the pregnant mother to prevent non-specific respiratory distress

Last update: **2021-02-19, 1399/12/01**

Update count: **0**

Registration date

2021-02-19, 1399/12/01

Design

Clinical trial with control group, with parallel groups, one-way blind, randomized, phase 3 on 160 patient

Registrant information

Name

Hassan Boskabadi

Name of organization / entity

Mashhad University of Medical Sciences

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Settings and conduct

This study is performed in the gynecology and obstetrics department of Ghaem Hospital in Mashhad. 50000 Unit of vitamin D ampules are injected into the mothers of the group, but there is no additional intervention in the control group.

Recruitment status

Recruitment complete

Funding source

Participants/Inclusion and exclusion criteria

Inclusion Criteria: Pregnant mothers 37-32 weeks with labor symptoms Non-entry criteria: diabetic mothers, heart disease, Asthma Excluded Criteria: Infants with obvious congenital anomalies, congenital infections, death in the delivery room, substance abuse by the mother and severe asphyxia, Respiratory distress syndrome, pneumonia, Meconial aspiration syndrom, birth earlier than 4 hours after delivery and later than one week, the need for ventilation in the delivery room

Expected recruitment start date

2021-01-20, 1399/11/01

Expected recruitment end date

2021-08-23, 1400/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Intervention groups

Intervention group: Pregnant mothers 32-37 weeks with delivery symptoms who use 50,000 units of vitamins D
Control group: Pregnant mothers 32-37 weeks with delivery symptoms who do not use vitamin D

Scientific title

The effect of vitamin D intake in the mother during childbirth on the incidence of nonspecific respiratory distress

Main outcome variables

Present or absent respiratory distress in the early hours of life

Public title

The effect of vitamin D intake in the mother during

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20110807007244N7**

Registration date: **2021-02-19, 1399/12/01**

childbirth on the incidence of respiratory problems in infants

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Pregnant woman with gestational age 32-37 weeks

Exclusion criteria:

Congenital anomaly
Congenital infection
Death of newborn in the delivery room
Severe asphyxia
Mothers with drug abuse
Respiratory distress syndrome
Pneumonia
Transient tachypnea of newborn
Meconium aspiration syndrome

Age

No age limit

Gender

Female

Phase

2-3

Groups that have been masked

- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **160**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, block randomization will be used as a reliable randomization method that leads to a balanced allocation of individuals in treatment groups at the end of each block. For this purpose, a web-based online method is used to determine the size and number of random blocks. This online software has the ability to create random blocks with variable sizes depending on the researcher. Using this website, 20 blocks with variable sizes of 6, 8 and 10 are introduced for a total of 160 samples, which are identified by numbers 1 to 20. The content of each block is proportional to the size of that block, including an equal number of intervention and control groups, with the order will be different. Following the first mother, one of the blocks is randomly selected and assigned to one of the groups based on the order of the contents of the block. Following the next mother, the next item of the same block is selected and this process continues until the first block is finished. The next block is selected randomly from the remaining blocks and the above process is repeated until sampling is completed.

Blinding (investigator's opinion)

Single blinded

Blinding description

The final outcome assessor i.e the researcher who will ultimately evaluate the children in terms of the outcome of the study, is blinded of group allocations

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Mashhad University of Medical Sciences

Street address

Ethics committee of Mashhad University of Medical Sciences, Ghoraeshi building, Daneshgah St.

City

Mashhad

Province

Razavi Khorasan

Postal code

9138813944

Approval date

2020-10-27, 1399/08/06

Ethics committee reference number

IR.MUMS.MEDICAL.REC.1399.613

Health conditions studied

1

Description of health condition studied

Non specific respiratory distress

ICD-10 code

P22.8

ICD-10 code description

Other respiratory distress of newborn

Primary outcomes

1

Description

Present or absent respiratory distress

Timepoint

During the first 12 hours of birth

Method of measurement

Count the number of respiratory rate

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Pregnant mothers with a gestational age of 37-32 weeks with delivery symptoms, in four hours to three days before delivery, receive 50,000 units (one sixth of an ampoule) of injectable vitamin D, made by Caspian factory.

Category

Prevention

2**Description**

Control group: Pregnant mothers with gestational age 32-37 weeks do not receive intervention.

Category

Other

Recruitment centers**1****Recruitment center****Name of recruitment center**

Ghaem Hospital

Full name of responsible person

Hassan Boskabadi

Street address

Neonatal Intensive care unite(NICU), Ghaem Hospital, Ahmadabad ST

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

Mashhad University of Medical Sciences

Full name of responsible person

Mohsen Tafaghodi

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Vice Chancellor for Research,Ghoraeshi building, Daneshgah St.

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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

Mashhad 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**

Mashhad University of Medical Sciences

Full name of responsible person

Hassan Boskabadi

Position

Professor

Latest degree

Subspecialist

Other areas of specialty/work

Pediatrics

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

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Latest degree

Subspecialist

Other areas of specialty/work

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Person responsible for updating data

Contact

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Latest degree

Subspecialist

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

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

Data Dictionary

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

Title and more details about the data/document

Effect of vitamin d on NRDS

When the data will become available and for how long

After completing the study

To whom data/document is available

Mashhad University of Medical Sciences Research Vice Chancellor

Under which criteria data/document could be used

According to the research deputy of Mashhad University of Medical Sciences

From where data/document is obtainable

Mashhad University of Medical Sciences Research Vice Chancellor

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

Request of Mashhad University of Medical Sciences Research Vice Chancellor

Comments