

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 May 2026

The effect of vitamin D administration during labor on the incidence of Transient Tachypnea of the Newborn

Protocol summary

Study aim

Determining the effect of maternal vitamin D intake during labor on the incidence of transient neonatal tachypnea

Design

Clinical trial with control group, parallel groups, single blind, randomized with a sample size of 80 people in any groups from March 2020 to November 2020

Settings and conduct

In the midwifery and maternity ward of the Ghaem hospital of Mashhad, the mothers of the two groups are selected and the intervention group receives vitamin D. The researcher examines the infants without knowing the mothers group and examines them for the presence or absence of Transient Tachypnea of the Newborn. Vitamin D levels will be measured from mother and baby during delivery.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Mothers with gestational age greater than 32 weeks who have delivery symptoms will be enrolled in the study. Exclusion criteria: Mothers with asthma

Intervention groups

Intervention group: Before delivery, one sixth vial of vitamin D (50,000 units) made by Caspian factory is injected. Control group: They do not receive vitamin D.

Main outcome variables

transient tachypnea of newborn

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20110807007244N5**

Registration date: **2020-12-01, 1399/09/11**

Registration timing: **retrospective**

Last update: **2020-12-01, 1399/09/11**

Update count: **0**

Registration date

2020-12-01, 1399/09/11

Registrant information

Name

Hassan Boskabadi

Name of organization / entity

Mashhad University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 915 515 3987

Email address

boskabadih@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-02-20, 1398/12/01

Expected recruitment end date

2020-10-30, 1399/08/09

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of vitamin D administration during labor on the incidence of Transient Tachypnea of the Newborn

Public title

The effect of vitamin D administration during labor on the incidence of Transient rapid breathing of the Newborn

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Pregnant mothers upper 32 weeks with delivery symptoms

Exclusion criteria:

Mothers with asthma post term pregnancy

Age

No age limit

Gender

Both

Phase

3

Groups that have been masked

- Care provider
- 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, using Random Allocation Software, a block randomization list with different sizes 4 or 6 is prepared, then according to the order of the contents of the blocks, which includes the group's name and unique identification code, each patient is assigned to one of the groups

Blinding (investigator's opinion)

Single blinded

Blinding description

By referring the mother, the midwife accidentally opens one of the blocks and, without knowing the grouping, presents one of the numbers to a researcher who is aware of the type of group. The researcher injects 50000 IU from ampoule of vitamin D into the mother of the intervention group. The infant will be followed up by the principal investigator who is unaware of the type of group, of the presence or absence of transient tachypnea of newborn. Data entry in SPSS is done as groups A and B, and the data analyst is unaware from the intervention or control group.

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, 3rd Floor, ghorashi building, Daneshgah St.

City

Mashhad

Province

Razavi Khorasan

Postal code

9138813944

Approval date

2020-06-24, 1399/04/04

Ethics committee reference number

IR.MUMS.MEDICAL.REC.1399.329

Health conditions studied

1

Description of health condition studied

Transient tachypnea of newborn

ICD-10 code

P22.1

ICD-10 code description

Transient tachypnea of newborn

Primary outcomes

1

Description

Frequency of transient tachypnea of newborn

Timepoint

1-3 days after neonatal birth

Method of measurement

Clinical and radiological signs and clinical course of transient tachypnea of newborn

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Pregnant mothers with symptoms of labor with a gestational age of more than 32 weeks 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 labor symptoms with gestational age more than 32 weeks do not receive intervention.

Category
Prevention

Country of origin
Type of organization providing the funding
Academic

Recruitment centers

1

Recruitment center

Name of recruitment center
Ghaem Hospital
Full name of responsible person
Hassan Boskabadi
Street address
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 and Technology, Qureshi Building, University St.
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Tafaghodim@mums.ac.ir
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

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
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Person responsible for scientific inquiries

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Person responsible for updating data

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Full name of responsible person

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Latest degree

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

There is no further information

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not 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