

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 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

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

Dear IRCT Director Please correct the start and end dates of the project as follows if possible Thank you IRCT registration number: IRCT20110807007244N5
Registration date: 2020-07-01, 1399/04/11 Registration timing: retrospective Last update: 2020-07-01, 1399/04/11 Registration date 2020-07-01, 1399/04/11
Expected recruitment start date 2021-01-19, 1399/10/30

Expected recruitment end date 2024-08-29, 1405/04/06

Approval date Ethic: 2020-06-24, 1399/04/04

Acronym

IRCT registration information

IRCT registration number: **IRCT20110807007244N5**

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

Registration timing: **prospective**

Last update: **2026-07-11, 1405/04/20**

Update count: **1**

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

2021-01-19, 1399/10/30

Expected recruitment end date

2024-08-29, 1403/06/08

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 bulding, 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

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.

City

Mashhad

Province

Razavi Khorasan

Postal code

9176699199

Phone

+98 51 3841 2069

Email

Boskabadih@mums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Mohsen Tafaghodi

Street address

Vice Chancellor for Research and Technology,
Ghoreshi Building, University St.

City

Mashhad

Province

Razavi Khorasan

Postal code

9176699199

Phone

+98 51 3841 2081

Email

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

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

Street address

NICU, Pediatrics Dep, Ghaem Hospital, Ahmadabad St.

City

Mashhad

Province

Razavi Khorasan

Postal code

9176699199

Phone

00988412069

Email

Boskabadih@mums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Hassan Boskabadi

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Person responsible for updating data**Contact****Name of organization / entity**

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Razavi Khorasan

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9176699199

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