

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 Jul 2026

The effect of vitamin D intake in mothers with preterm labor on prognosis of children at two years of age

Protocol summary

Study aim

determination Effect of Vitamin D Intake on Maternal of Delivery on prognosis at two years

Design

A concealed, randomized, blinded, controlled clinical trial with a parallel group design of 122 mother, enrolled between January 2020 and September 2021

Settings and conduct

The design will be a one-blind clinical trial under the supervision of Mashhad University of Medical Sciences in 1398-1400. Premature infants less than 37 weeks gestation of mothers receiving vitamin D (the intervention group who received 50,000 units of vitamin D injections 72 hours before delivery) were compared with infants of mothers who did not receive vitamin D at two years of age. Evaluation of children's development is performed with the Denver-2 test. The level of vitamin D in the mother and infant is measured.

Participants/Inclusion and exclusion criteria

Included: Pregnant mothers less than 37 weeks with delivery symptoms Excluded: History of developmental delay in the family

Intervention groups

Pregnant mothers who are less than 37 weeks old with symptoms of delivery who have received vitamin D as an intervention group and mothers who have not received vitamin D as a control group are included in the study.

Main outcome variables

Child Development at two years

General information

Reason for update

Acronym

Vitamin D prognosis

IRCT registration information

IRCT registration number: **IRCT20110807007244N4**

Registration date: **2020-06-26, 1399/04/06**

Registration timing: **registered_while_recruiting**

Last update: **2020-06-26, 1399/04/06**

Update count: **0**

Registration date

2020-06-26, 1399/04/06

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

2019-11-22, 1398/09/01

Expected recruitment end date

2022-11-22, 1401/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of vitamin D intake in mothers with preterm labor on prognosis of children at two years of age

Public title

The effect of vitamin D intake of mother in labor on the prognosis of premature children

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:
Pregnant woman with gestational age less than 37 weeks with symptoms of labor

Exclusion criteria:
Infants with a history of known neuro degenerative diseases in the family congenital anomaly congenital infection death in the delivery room Severe asphyxia mothers with drug abuse

Age
No age limit

Gender
Both

Phase
2-3

Groups that have been masked

- Care provider
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size
Target sample size: **50**

Randomization (investigator's opinion)
Randomized

Randomization description
Randomization is based on simple random method using table of random numbers

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(prognosis), 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
Ahmadabad ST.

City
mashhad

Province
Razavi Khorasan

Postal code
9138813944

Approval date

2019-11-19, 1398/08/28

Ethics committee reference number
IR.MUMS.MEDICAL.REC.1399.078

Health conditions studied

1

Description of health condition studied
Vitamin D Deficiency, prematurity,Child Prognosis

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Evaluation of child development

Timepoint
6,12 and 18 month

Method of measurement
denver developmental screening test

Secondary outcomes

1

Description
Child development

Timepoint
Two years

Method of measurement
denver developmental screening test

Intervention groups

1

Description
Pregnant mothers less than 37 weeks with delivery symptoms who injected one dose of 50,000 units of vitamin D within 72 hours before delivery as intervention groups.

Category
Prevention

2

Description
Control group: No intervention. In mothers of control group, routine cares will be done.

Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center

Ghaem Hospital
Full name of responsible person
Hassan Boskabadi
Street address
Ahmadabad ST.
City
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91766-99199
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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
Street address
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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

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Person responsible for updating data

Contact

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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

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

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

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