Clinical Trial Protocol
Iranian Registry of Clinical Trials

30 Oct 2026

Effect of vitamin D on pancreatic function and controlling of type 1 diabetes mellitus

Protocol summary

Study aim
Effect of vitamin D on pancreatic function and controlling of type 1 diabetes mellitus
Design
Clinical trial without control group; the sample size includes all of the eligibility criteria that 30-sample are predictable, phase 2 clinical trial.
Settings and conduct
This clinical trial study was performed will be selected by an inhomogeneous method in patients with type 1 diabetes mellitus referring to Amirkola Children's Hospital Endocrinology Clinic.
Participants/Inclusion and exclusion criteria
Inclusion criteria: children who have been diagnosed with type 1 diabetes mellitus in the last five years and they referred to Endocrinology Clinic of Amirkola Children's Hospital; C-peptid above 0.2 nanomol per liter; Vitamin D level lower than 30 nano-gram per milliliter; Calcium above 0.8 milligram per deciliter Exclusion criteria: not modify vitamin D after a course of vitamin D deficiency treatment.
Intervention groups
Type 1 diabetes mellitus children with a vitamin D level below 30 nanogram per mililiter will be treated with 50000 IU Pearl vitamin D for 9 months. The patients' C-peptide, 25OH (D), HbA1C and total daily insulin dose will be compared at the beginning and end of the study.
Main outcome variables
C-peptide; 25OH (D); HbA1C; Total daily insulin dose

General information

Reason for update
Acronym
(Vitamin D (VD), Type 1 diabetes mellitus (T1DM
IRCT registration information
IRCT registration number: **IRCT20180228038900N2**
Registration date: **2018-07-30, 1397/05/08**
Registration timing: **retrospective**
Last update: **2018-09-09, 1397/06/18**
Update count: **2**
Registration date
2018-07-30, 1397/05/08

Registrant information
Name
Morteza Alihanpour Aghamaleki
Name of organization / entity
Country
Iran (Islamic Republic of)
Phone
+98 11 3234 6963
Email address
m.alijanpour@mubabol.ac.ir

Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2016-09-22, 1395/07/01
Expected recruitment end date
2017-11-01, 1396/08/10
Actual recruitment start date
2016-09-22, 1395/07/01
Actual recruitment end date
2017-11-01, 1396/08/10
Trial completion date
empty

Scientific title
Effect of vitamin D on pancreatic function and controlling of type 1 diabetes mellitus

Public title
Effect of vitamin D on pancreas and controlling of T1DM
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Children who have been diagnosed with type 1 diabetes

mellitus in the last five years and they referred to Endocrinology Clinic of Amirkola Children's Hospital C-peptid above 0.2 nanomol per liter Vitamin D level lower than 30 nano-gram per milliliter Calcium above 8.5 milligram per deciliter

Exclusion criteria:

Not modify vitamin D after a course of vitamin D deficiency treatment

Age

No age limit

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **40**

Actual sample size reached: **30**

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Single

Other design features

The patients' C-peptide (as a marker of β-cells function), HbA1C and total daily dose (TDD) insulin (as markers of T1DM controlling) and 25 (OH) D were compared at the beginning and end of the study.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Babol University of Medical Sciences

Street address

Vice- Chancellor for Research Technology Affairs, Babol University of Medical Sciences, Ganjafroz Street

City

Babol

Province

Mazandaran

Postal code

4717647745

Approval date

2016-11-09, 1395/08/19

Ethics committee reference number

IR.MUBABOL.REC.1395.48

Health conditions studied

1

Description of health condition studied

Type 1 diabetes mellitus

ICD-10 code

E10

ICD-10 code description

Type 1 diabetes mellitus

Primary outcomes

1

Description

C-peptide

Timepoint

At the beginning of the study (before intervention) and end of study (9 months after starting treatment)

Method of measurement

Blood serum level

2

Description

Hemoglobin A1C

Timepoint

At the beginning of the study (before intervention) and end of study (9 months after starting treatment)

Method of measurement

Blood serum level

3

Description

Total daily dose of Insuline

Timepoint

At the beginning of the study (before intervention) and every 3 months until end of study (9 months after starting treatment)

Method of measurement

Question of the parents of patient children (recorded in questionnaire)

4

Description

Vitamin D

Timepoint

At the beginning of the study (before intervention) and based on vitamin D level, 6 or 8 weeks later and if modified, end of study

Method of measurement

Blood serum level

Secondary outcomes

empty

Intervention groups

1

Description

Type 1 diabetes mellitus children who had been treated with long-acting insulin (glargine) and fast-acting insulin (aspart) based on the Basal Bolus Insulin Protocol (BBIP) in the last five years, with at least 6 months after the onset of their diabetes will be selected as the sample and their C-peptide levels will be tested, initially. The, those children who have basal C-peptide levels> 0.2 nmol/l will be tested for vitamin D (VD) levels. Those with 25(OH) D levels lower than 30 (ng/ml), which means decreased level of VD, will be included in the study. If their VD level be between 20 and 30 (ng/ml), indicating VD insufficiency, they will receive D-VITIN 50000U PEARL per week for up to 6 weeks, and if their VD level be lower than 20 (ng/ml), which indicates VD deficiency (15), they will receive D-VITIN 50000U PEARL for up to 8 weeks. Then, the children's VD levels will be re-tested and if it will be shown to be low, the weekly treatment with the same previous level will be continued until they have normal VD levels (more than 30 (ng/ml). If they will fail to reach a normal level of this vitamin after another six-to-eight-week period of D-VITIN PEARL, the patients will be excluded from the study. After correcting the patients' levels of VD, a single dose of VD will be administered for each month until the end of the study (9 months) and finally, their C-peptide, 25OH (D), and HbA1C levels will be checked again and their C-peptide, 25OH (D), HbA1C and TDD will be compared at the beginning and end of the study. Insulin Lantus (Glargine) was manufactured by SANOFI-Aventis Germany and Insulin Novorapid (aspart) was manufactured by NOVO NORDISK A/S, a Danish multinational pharmaceutical company. D-VITIN 50000U PEARL was manufactured by Zahravi Pharmaceutical Company in Iran. To check the above, we needed 3 cc of blood clots. C-peptide will be measured by the ELISA method using a Diasorin kit produced in Italy, VD will be measured by the ELISA method using the Ids kit made in England and HbA1C will be measured by an enzymatic method using a Pishtazteb kit made in Iran, and the results will be recorded.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Amirkola Children’s Hospital
Full name of responsible person
Morteza Alijanpour Aghamaleki
Street address
Amirkola Children’s Hospital, Street No. 19
City
Babol
Province
Mazandaran
Postal code
4731741151
Phone
+98 11 3234 6963
Fax
+98 11 3234 6963
Email
m.alijanpour@yahoo.com
Web page address
http://amirkola.mubabol.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Babol University of Medical Sciences
Full name of responsible person
Dr Reza Ghadimi
Street address
Vice- Chancellor for Research Technology Affairs, Babol University of Medical Sciences, Ganjafroz Street
City
Babol
Province
Mazandaran
Postal code
4717647745
Phone
+98 11 3219 7667
Email
r.ghadimi@mubabol.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Babol 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
Babol University of Medical Sciences
Full name of responsible person
Morteza Alihanpour Aghamaleki
Position
Assistant professor
Latest degree
Subspecialist
Other areas of specialty/work
Pediatrics

Street address
No19
City
Babol
Province
Mazandaran
Postal code
4731741151
Phone
+98 11 3234 6963
Fax
+98 11 3234 6963
Email
m.alijanpour@mubabol.ac.ir

Person responsible for scientific inquiries

Contact
Name of organization / entity
Babol University of Medical Sciences
Full name of responsible person
Morteza Aljanpour Aghamaleki
Position
Assistant Professor
Latest degree
Subspecialist
Other areas of specialty/work
Pediatrics
Street address
No 19
City
Babol
Province
Mazandaran
Postal code
4731741151
Phone
+98 11 3234 6963
Fax
+98 11 3234 6963
Email
m.alijanpour@mubabol.ac.ir
Web page address
http://amirkola.mubabol.ac.ir/

Person responsible for updating data

Contact
Name of organization / entity
Babol University of Medical Sciences
Full name of responsible person
Dr Zahra Oruji
Position
Pediatrics Residency
Latest degree
Medical doctor
Other areas of specialty/work
Pediatrics
Street address
No 19
City
Babol- Amirkola
Province
Mazandaran
Postal code
4731741151
Phone
+98 11 3234 6963
Email
dr.oruji@yahoo.com

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
Undecided - It is not yet known if there will be 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
Undecided - It is not yet known if there will be 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
-
When the data will become available and for how long
-
To whom data/document is available
Public access
Under which criteria data/document could be used
...
From where data/document is obtainable
Dr Morteza Alijanpour
What processes are involved for a request to access data/document
Email as soon as possible.
Comments