Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Evaluation the effect of two doses of BCG vaccine on inflammatory factors in the glycemic control on type 1 diabetic patients, a quasi-experimental clinical trial

Protocol summary

Study aim

Determining the effect of BCG vaccine on glycemic control in type 1 diabetic patients and mean levels of HbA1C, FBS, Anti-GAD and Anti ICA, CBC, NBT and Total IgA before and after BCG vaccine injection. Determine the average HbA1C level every three months for one year.

Design

Clinical trial phase 2 to determine efficacy in 16 patients. The sample size was determined by the results of a valid study in SPSS software.

Settings and conduct

After being called to the Diabetes Center, the conditions for the admission of volunteer patients will be examined. Patients with inclusion criteria are referred to the laboratory of Diabetes Center for testing after collecting basic information. At the beginning of the study and one year after treatment, HbA1C, FBS, Anti-GAD, Total IgA, Anti ICA, NBT and CBC tests will be performed. The vaccine will be injected twice. We will not make any intervention or change in the main treatment of patients. Follow-up of patients will continue with HbA1C measurement every three months. It should be noted that patients will be excluded from the study if the second dose is not used.

Participants/Inclusion and exclusion criteria

Patients 6 to 14 years old with type 1 diabetes who have been suffered for at least one year and have received a full dose of insulin.with a Hb A1C level above 7. People without these conditions are not allowed to enter the study.

Intervention groups

HbA1C, FBS, Anti-GAD and Anti ICA, Total IgA, NBT and CBC tests will be performed at the beginning of the study and one year after receiving treatment. The vaccine is given at the same dose for two consecutive months and then patients are followed up every three months by recording HbA1C.

Main outcome variables

HbA1C;FBS;Age;Gender;insulin; Anti-GAD antibody;Anti ICA;Total IgA;CBC NBT

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20201012049003N1**
Registration date: **2020-10-15, 1399/07/24**
Registration timing: **prospective**

Last update: **2020-10-15, 1399/07/24**
Update count: **0**

Registration date

2020-10-15, 1399/07/24

Registrant information

Name

Mahtab Ordooei

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 35 3728 0228

Email address

dr.ordooei@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-10-16, 1399/07/25

Expected recruitment end date

2020-11-15, 1399/08/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation the effect of two doses of BCG vaccine on inflammatory factors in the glycemic control on type 1 diabetic patients, a quasi-experimental clinical trial

Public title

Effect of BCG in treatment of diabetes type 1

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

HbA1C>7 Get the full dose of insulin having diabetes for at least 1 year (to pass the Honeymoon course) Age category 6 to 14 years

Exclusion criteria:

retinopathy Nephropathy Diabetic neuropathy Macrovascular complications of diabetes HbA1C<7 New cases of type 1 diabetes Having a recurrent infection or a history of allergy to the vaccine at birth Take high doses of corticosteroids History of immunodeficiency disease celiac

Age

From **6 years** old to **14 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **16**

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of yazd University of Medical Sciences

Street address

Central Administration, Bahonar Sq., Yazd 8916978477 I.R. Iran

City

Yazd

Province

Yazd

Postal code

8916978477

Approval date

2020-04-28, 1399/02/09

Ethics committee reference number

IR.SSU.REC.1399.023

Health conditions studied

1

Description of health condition studied

Diabetes type1

ICD-10 code

E10.1

ICD-10 code description

Type 1 diabetes mellitus with ketoacidosis

Primary outcomes

1

Description

HbA1c level in patients

Timepoint

Measurement of HbA1c at the beginning of the study and 3, 6, 9, and 12 months after the first vaccine was given

Method of measurement

blood test

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Diabetes type1 patients, BCG vaccine, two injections at one month intervals

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Yazd Diabetes Research Center

Full name of responsible person

Mahtab Ordooei

Street address

Yazd Diabetes Research center, Art Hall Alley, Shahid

Sadoughi Blvd., Bahonar Sq., Yazd, Iran
City
Yazd
Province
Yazd
Postal code
8917693571
Phone
+98 35 3728 0226
Email
dr.ordooei@yahoo.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Yazd University of Medical Sciences
Full name of responsible person
Mahtab Ordooei
Street address
Yazd Diabetes Research center, Art Hall Alley, Shahid Sadoughi Blvd., Bahonar Sq., Yazd, Iran
City
Yazd
Province
Yazd
Postal code
8917693571
Phone
+98 35 3728 0226
Email
diabet_center@yahoo.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Yazd 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
Yazd University of Medical Sciences
Full name of responsible person
Mahtab Ordooie
Position
Associate professor
Latest degree
Subspecialist
Other areas of specialty/work
Internal Medicine
Street address
Yazd Diabetes Research center, Art Hall Alley, Shahid Sadoughi Blvd., Bahonar Sq., Yazd, Iran
City
Yazd
Province
Yazd
Postal code
8917693571
Phone
+98 35 3728 0226
Email
dr.ordooei@yahoo.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Yazd University of Medical Sciences
Full name of responsible person
Mahtab Ordooei
Position
Associate professor
Latest degree
Subspecialist
Other areas of specialty/work
Internal Medicine
Street address
Yazd Diabetes Research center, Art Hall Alley, Shahid Sadoughi Blvd., Bahonar Sq., Yazd, Iran
City
Yazd
Province
Yazd
Postal code
8917693571
Phone
+98 35 3728 0226
Email
dr.ordooei@yahoo.com

Person responsible for updating data

Contact
Name of organization / entity
Yazd University of Medical Sciences
Full name of responsible person
Mahtab Ordooei
Position
Associate professor
Latest degree
Subspecialist
Other areas of specialty/work
Internal Medicine
Street address
Yazd Diabetes Research center, Art Hall Alley, Shahid Sadoughi Blvd., Bahonar Sq., Yazd, Iran

City
Yazd
Province
Yazd
Postal code
8917693571
Phone
+98 35 3728 0226
Email
dr.ordooei@yahoo.com

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 more information.

Study Protocol
Undecided - It is not yet known if there will be 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
Not applicable