Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

The effect of BCG vaccination in treatment of patients with type 1 diabetes mellitus

Protocol summary

Summary

The aim of this study is the evaluation of effect of BCG vaccination in treatment of patients with type 1 diabetes mellitus. Fifty- two patients with type 1 diabetes mellitus will enrolled who treated with insulin for ≥ 10 years. The place of study will be clinic of diabetes in Ali-asghar Hospital affiliated to Shiraz University of Medical Sciences. A questionnaire including age, sex, duration of disease, amount of daily insulin and so on will record by a physician. The patients with duration of insulin therapy more than 10 years, negative HIV, negative tuberculin test, HbA1C lower than 8% will participate in this study. The patients will be randomized to two groups: interventional and control group. In interventional group, the patients will take BCG vaccination 0.2 cc intradermal in deltoid muscle in baseline, 4 weeks later, 1 year after the first dose. In control group will be the same except normal saline instead BCG. Measuring fasting blood sugar, C-peptide, HbA1C will be done.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017042919940N2**
Registration date: **2017-05-29, 1396/03/08**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2017-05-29, 1396/03/08

Registrant information

Name

Mozhgan Moghtaderi

Name of organization / entity

Allergy Research Center- Shiraz University of Medical Sciences, Shiraz, Iran

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

vice- chancellor for research, Shiraz University of Medical Sciences, Sayed Basir Hashemi Grant number is 95-01-106-11565

Expected recruitment start date

2017-06-01, 1396/03/11

Expected recruitment end date

2018-06-01, 1397/03/11

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of BCG vaccination in treatment of patients with type 1 diabetes mellitus

Public title

The effect of BCG vaccination in treatment of patients with type 1 diabetes mellitus

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion Criteria: patients with type 1 diabetes mellitus Duration of insulin injection at least for 10 years Age 18 to 55 years negative HIV antibody Hb A1C < 8% negative tuberculin test Exclusion criteria: pregnancy Having tuberculosis infection recent or before Using immunosuppressive medications Hb A1C > 8% Using

high dose of aspirin(> 160 mg per day) Having HIV infection

Age
From **18 years** old to **55 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **52**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features
Randomization will be based on random numbers

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Shiraz University of Medical Sciences

Street address
Zand strret

City
Shiraz

Postal code

Approval date
2016-10-01, 1395/07/10

Ethics committee reference number
IR.SUMS.REC.1395.109-11565

Health conditions studied

1

Description of health condition studied
Endocrine disease

ICD-10 code
E10-E14

ICD-10 code description
E10-E14

Primary outcomes

1

Description
fasting blood sugar

Timepoint
0-1-3-4-8-12-16-20-24-28-32-36-40-44-48-52 weeks after intervention

Method of measurement
Glucometer

Secondary outcomes

1

Description
HbA1C

Timepoint
0-4 -8- 12- 20- 32- 44-52 weeks after starting the study

Method of measurement
Enzymatic method

Intervention groups

1

Description
In interventional group, the patients will take BCG vaccination 0.2 cc intradermal in deltoid muscle in baseline, 4 weeks later, 1 year after the first dose.

Category
Treatment - Drugs

2

Description
In control group, the patients will take normal saline 0.2 cc intradermal in deltoid muscle in baseline, 4 weeks later, 1 year after the first dose.

Category
Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
Ali- Asghar Allergy Clinic

Full name of responsible person
Mozhgan Moghtaderi

Street address
Meshkinfam Avenue

City
Shiraz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Vice chancellor for research, Shiraz University of

Medical Sciences
Full name of responsible person
Seyed Basir Hashemi
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Grant name
95-01-106-11565
Grant code / Reference number
95-01-106-11565
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice chancellor for research, Shiraz University of Medical Sciences
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty