

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

13 Jun 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  $\geq 10$  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)

##### Phone

+98 71 3630 2587

##### Email address

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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  
**Street address**  
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**City**  
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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

**Contact**  
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## Person responsible for updating data

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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*