

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

26 Jun 2026

### Comparison of surgical techniques in the treatment of suppurative lymphadenitis caused by BCG vaccination

#### Protocol summary

##### Summary

BCG vaccination is the national immunization program in Iran and its lymphadenopathy is relatively common finding in children. Variety of Therapies for the treatment of suppurative lymphadenitis caused by BCG vaccination has been recommended. Given the existing differences, we decided to design a study to evaluate and compare different surgical procedures effects on (needle aspiration, incision and drainage or excision) the treatment of suppurative lymphadenitis caused by BCG vaccination. Inclusion criteria: All children involved with BCG lymphadenitis Exclusion criteria: The development of any systemic diseases such as malignant lymphadenopathy is the author of it; patients with a history of tuberculous meningitis or millitary tuberculosis All of the children that admitted to children Hospital of Tabriz during February of 2013 to 2014 February with diagnosis of suppurative lymphadenitis induced by BCG, After recording there information about age, sex, previous treatment and site of the lymphadenitis They will randomly assigned into three groups: The first group will be treated with needle aspiration The second group will be treated by the method of incision and drainage The third group will undergo total excision of lymphadenitis In continue patients will be follow up for 6 months. In this term rate of recovery, side effects of surgery (Damage to nerves, scar, and formation of colloid) and relapse is examined.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2015011420663N1**  
Registration date: **2015-04-29, 1394/02/09**  
Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2015-04-29, 1394/02/09

##### Registrant information

###### Name

Davoud Badebarin

###### Name of organization / entity

###### Country

Iran (Islamic Republic of)

###### Phone

+98 41 3526 2257

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##### Recruitment status

###### Recruitment complete

##### Funding source

Tabriz University of Medical Science

##### Expected recruitment start date

2013-01-20, 1391/11/01

##### Expected recruitment end date

2014-01-21, 1392/11/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Comparison of surgical techniques in the treatment of suppurative lymphadenitis caused by BCG vaccination

##### Public title

Surgical treatment of BCG induced suppurative lymphadenitis

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

Inclusion criteria: The risk of BCG lymphadenitis

Exclusion criteria: The development of any systemic diseases such as malignant lymphadenopathy is the author of it ; patients with a history of tuberculous meningitis or tuberculosis millary

#### **Age**

From **1 day** old to **6 months** old

#### **Gender**

Both

#### **Phase**

N/A

#### **Groups that have been masked**

*No information*

#### **Sample size**

Target sample size: **39**

#### **Randomization (investigator's opinion)**

N/A

#### **Randomization description**

#### **Blinding (investigator's opinion)**

Not blinded

#### **Blinding description**

#### **Placebo**

Not used

#### **Assignment**

Parallel

#### **Other design features**

### **Secondary Ids**

empty

### **Ethics committees**

#### **1**

##### **Ethics committee**

###### **Name of ethics committee**

Tabriz University of Medical Science

###### **Street address**

Unit of Ethics Committee, Medical Faculty, Golgasht street

###### **City**

Tabriz

###### **Postal code**

##### **Approval date**

2013-07-22, 1392/04/31

##### **Ethics committee reference number**

92102

### **Health conditions studied**

#### **1**

##### **Description of health condition studied**

BCG induced suppurative LYMPHADENITIS

##### **ICD-10 code**

Z23.2

##### **ICD-10 code description**

[Need for immunization against tuberculosis [BCG

### **Primary outcomes**

#### **1**

##### **Description**

Recovery from BCG lymphadenitis with 3 different surgical techniques

##### **Timepoint**

2 and 6 month after vaccine injection

##### **Method of measurement**

Clinical examination of recurrence

### **Secondary outcomes**

#### **1**

##### **Description**

Reviewing the formation of keloids, scars, skin indentations, deformity, edema

##### **Timepoint**

after six month

##### **Method of measurement**

clinical examination

### **Intervention groups**

#### **1**

##### **Description**

In the first group lymphadenitis caused by BCG vaccination can be treated by using needle aspiration, So that lymph node will be aspirated with needle number 21

##### **Category**

Treatment - Surgery

#### **2**

##### **Description**

In the second group in the first group lymphadenitis caused by BCG vaccination can be treated by using incision & drainage, So that lymph node will be incised on the maximum point of fluctuation. Site of the incision will be washed with normal saline then we place a drain in order to drainage our site.

##### **Category**

Treatment - Surgery

#### **3**

##### **Description**

In the third group lymph node will totally excised, first, the patient is underwent general anesthesia, then we will incise the skin and disconnect lymph nodes supportive tissues. Finally lymph nodes totally removed.

##### **Category**

Treatment - Surgery

### **Recruitment centers**

**1**

**Recruitment center**

**Name of recruitment center**  
children Hospital of Tabriz(Farman Farmanian)  
**Full name of responsible person**  
Dr .Aslan Abadi  
**Street address**  
Tabriz children hospital  
**City**  
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Golgasht street  
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**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**  
Tabriz University of Medical Science  
**Full name of responsible person**  
Dr. Aslan abadi  
**Street address**  
Tabriz children hospital(Farman Farmanian)  
**City**  
Tabriz  
**Grant name**  
**Grant code / Reference number**  
**Is the source of funding the same sponsor organization/entity?**  
Yes  
**Title of funding source**  
Tabriz University of Medical Science  
**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 scientific inquiries**

**Contact**

**Name of organization / entity**  
Tabriz University of Medical Science  
**Full name of responsible person**  
Dr. Saiid Aslan Abadi  
**Position**  
Sub Specialist of Children Surgery  
**Other areas of specialty/work**  
**Street address**  
Department of Pediatrics, Children Hospital of Tabriz,  
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+98 41 3526 2250  
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**Web page address**

**Person responsible for updating data**

**Contact**

**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*

**Person responsible for general inquiries**

**Contact**

**Name of organization / entity**  
Tabriz University of Medical Science  
**Full name of responsible person**  
Dr. Hosein Shiri  
**Position**  
General Surgery Resident  
**Other areas of specialty/work**  
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