Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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 milliary tuberculosis All of the children that admitted to children Hospital of Tabriz during February of 2013 to 2014February 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)
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+98 41 3526 2257
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badebarind@tbzmed.ac.ir

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 milliary

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
Tabriz

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 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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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 Surgey

Other areas of specialty/work

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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