

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Jul 2026

A comparison study of efficacy intralesional injection of tuberculin antigen and placebo in the treatment of multiple common warts

Protocol summary

Summary

Study of efficacy intralesional injection tuberculin antigen in the treatment of multiple common warts. A randomized, double-blind, placebo-controlled clinical trial. Patients and researchers were blinded. Inclusion criteria: Patients with multiple common warts with past history of BCG vaccination or positive tuberculin test PPD greater than 5 millimeter or obviously scar in the upper left arm, Multiple warts equally or more than three wart. Exclusion criteria: Pregnancy or lactation, Immunosuppressive patients, Past history of TB disease, Sever reaction such as anaphylaxis to tuberculin antigen, Any generalized dermatitis, receiving other treatments for wart, receiving first and second generation anti TB drugs. The study was carried out in dermatologic outpatient clinic, Ahvaz University Hospital, after obtaining the informed consent from all patients and parents of children. Our study included 54 patients with multiple common warts. Patient was classified into 2 groups: First group included 27 patients treated with IL (intra wart) tuberculin antigen with a dose of 0.1 ml by insulin syringe. Second group included 27 patients treated with IL saline with a dose of 0.1 ml. In both groups, injections were made into the largest one of the multiple common warts. Injections were repeated for all patients every one week for a total of six injections or less in cases of resolution of warts. At the first visit, the duration, location, number, diameter of all warts were reported. Response of distant, anatomically distinct, untreated warts was also noted. Response to treatment was evaluated by the decrease in size of warts and by photographic comparison. The response was considered complete if there was disappearance of 75-100% warts and return of normal skin marking , partial if the warts had regressed in size and number by 50-74% , minimal response if the was regressed in size and number by 25-49% and no response if the warts had regressed in size and number by leaser than 25%. Immediate and late adverse effects of tuberculin antigen were evaluated

after each treatment session. After the sixth injection, if wart was not completely healed, the patient refer for cryotherapy. Follow up was made every two months for six months to detect any recurrence.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015080323486N1**

Registration date: **2015-12-02, 1394/09/11**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2015-12-02, 1394/09/11

Registrant information

Name

Farzaneh Alamshahi

Name of organization / entity

Ahvaz JundiShapur of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Ahvaz Jundishapur University of Medical Sciences, Vice chancellor for research

Expected recruitment start date

2014-09-23, 1393/07/01

Expected recruitment end date

2015-10-22, 1394/07/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A comparison study of efficacy intralesional injection of tuberculin antigen and placebo in the treatment of multiple common warts

Public title

Study of efficacy injection tuberculin in the treatment of warts

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Patients with multiple common warts with past history of BCG vaccination or positive tuberculin test PPD greater than 5 millimeter or obviously scar in the upper left arm, Multiple warts equally or more than three wart. Exclusion criteria: Pregnancy or lactation, Immunosuppressive patients, Past history of TB disease, Sever reaction such as anaphylaxis to tuberculin antigen, Any generalized dermatitis, receiving other treatments for wart, receiving first and second generation anti TB drugs.

Age

From **15 years** old to **75 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **54**

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Double blinded

Blinding description**Placebo**

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Ahvaz Jundishpur University of Medical Sciences

Street address

Ahvaz Jundishapur University of Medical Sciences,
Golestan Blvd

City

Ahvaz

Postal code**Approval date**

2014-10-11, 1393/07/19

Ethics committee reference number

ajums.REC.1393.229

Health conditions studied**1****Description of health condition studied**

Multiple common warts

ICD-10 code

B07

ICD-10 code description

Viral warts

Primary outcomes**1****Description**

size and number of wart

Timepoint

at start of the study and at each episode of treatment

Method of measurement

measurement diameter of wart with ruler and by photographic comparison

Secondary outcomes**1****Description**

side effect

Timepoint

at each treatment session

Method of measurement

history and physical examination

2**Description**

recurrence of wart

Timepoint

Every two months for 6 months after complete response

Method of measurement

physical examination

Intervention groups**1****Description**

Intervention group:Injection of 0.1 ml PPD antigen into the largest one of warts at one week intervals for a

maximum of six treatments

Category

Treatment - Drugs

2

Description

Control groups:Injection of 0.1 ml normal saline into the largest one of the warts at one-week intervals for a maximum of six treatments.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Ahvaz Imam khomeini hospital-Dermatology clinic

Full name of responsible person

Street address

City

Ahvaz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ahvaz Jundishapur University of Medical Sciences,
Vice chancellor for research

Full name of responsible person

Nader saki

Street address

Ahvaz University of Medical Sciences , University
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City

Ahvaz

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Ahvaz Jundishapur University of Medical Sciences, Vice
chancellor for research

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

Ahvaz Jundishapur University of Medical Sciences,
Vice chancellor for research

Full name of responsible person

Farzaneh Alamshahi

Position

Resident of Dermatology

Other areas of specialty/work

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full professor

Other areas of specialty/work

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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