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

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Name of organization / entity
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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 Town, Ahvaz

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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Position

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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