

Clinical Trial Protocol

Iranian Registry of Clinical Trials

25 Sep 2026

Comparison of efficacy of application viable BCG vaccine paste versus placebo in the treatment of common wart: a double-blind and randomized placebo-control clinical trial

Protocol summary

Summary

Comparison of efficacy of application viable BCG vaccine paste in the treatment of common wart versus placebo: a double-blind and randomized placebo-control clinical trial. Abstract: Treatment of verrucae is difficult and may be painful or scarring especially by using traditional destructive methods . The aim of current study is evaluation of the efficacy and safety of topical application of viable Bacillus Calmette-Guerine (BCG) in the form of paste as a new and safe immunotherapeutic modality in treatment of common warts. Method and material: This double blind randomized clinical trial study is carried out in patients who were divided into two groups: patients in case group (40 patients) receive topical BCG paste (BCG+salicylic acid +glycerin) and patients in control group (40 patients) receive placebo (salicylic acid+glycerin) with similar shape and color of the BCG paste. Treatment protocols in two groups are topical weekly application for 8 consecutive weeks. patients who have no response in both group will be treat by cryotherapy. Follow up will be done every 2 weeks during treatment and 8 weeks after the end of treatment for evaluation of recurrence .

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014101419527N1**
Registration date: **2015-10-21, 1394/07/29**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2015-10-21, 1394/07/29

Registrant information

Name

Sedighe Tavakoli

Name of organization / entity

Jundishapur University of Medical Science, Ahvaz

Country

Iran (Islamic Republic of)

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+98 29 21837

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Recruitment status

Recruitment complete

Funding source

Ahvaz Jundishapur University Sciences

Expected recruitment start date

2014-11-22, 1393/09/01

Expected recruitment end date

2015-11-22, 1394/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of efficacy of application viable BCG vaccine paste versus placebo in the treatment of common wart: a double-blind and randomized placebo-control clinical trial

Public title

Treatment of common wart with topical BCG vaccine

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: patients with common wart without any limitation on patients age; patients sex; wart numbers;

distribution of lesions; duration of disease. Exclusion criteria: any treatment in the 3 months ago; no BCG immunization; no immune deficiency due to drug or chronic disease; hypersensitivity to BCG; presence of febrile disease; chronic disease induced immunodeficiency such as diabetes melitus; presence of allergic skin disease such as urticaria.

Age

From **1 year** old to **70 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **40**

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

Ahwaz Jundishapur University of Medical Science

Street address

Department of Development Research and Technology ahwaz jundishapur University of Medical Sciences and Health care, University town, Ahwaz

City

Ahwaz

Postal code

61357-15794

Approval date

2014-10-04, 1393/07/12

Ethics committee reference number

13930210

Health conditions studied

1

Description of health condition studied

common wart

ICD-10 code

B07

ICD-10 code description

Viral warts

Primary outcomes

1

Description

Wart size change

Timepoint

Every 2 week

Method of measurement

With ruler

Secondary outcomes

1

Description

Erythema, Bleeding, Pain

Timepoint

Every week

Method of measurement

Questionnaire

Intervention groups

1

Description

interventional group: in this group 40 patients treat with topical BCG weekly for 8 consecutive week. 1 cc BCG and 3cc glycerin combine and apply on warts. dress with plastic and wash after 2 hours. patients evaluate every 2 week for complications, response to treatment and photography. patients also evaluate for recurrence 8 week after end of treatment. cryotherapy will be done if not response to BCG.

Category

Treatment - Drugs

2

Description

control group: in this group 40 patients treat with topical glycerin weekly for 8 consecutive week. 3cc glycerin apply on warts. dress with plastic and wash after 2 hours. patients evaluate every 2 week for complications, response to treatment and photography. patients also evaluate for recurrence 8 week after end of treatment. cryotherapy will be done if not response to glycerin.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Ahwaz Emam Khomeini hospital dermatology department

Full name of responsible person

Tavakoli Sedighe, Dermatology resident

Street address

Dermatology department, Emam Khomeini hospital, Ahvaz

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Ahwaz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ahwaz Jundishapur University of Medical Science

Full name of responsible person

Ahwaz Jundishapur University of Medical Science

Street address

Ahwaz Jundishapur University of Medical Science

City

Ahwaz

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Ahwaz Jundishapur 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

Ahwaz Jundishapur University of Medical Sciences

Full name of responsible person

Tavakoli Sedighe

Position

Medicine/Dermatology Residence

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

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Dermatologist

Other areas of specialty/work

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Web page address

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