

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Jul 2026

A comparative study on the adverse reactions of purified chick embryo cell vaccine (PCEC) and purified vero cell rabies vaccine (VERO) administered intramuscular as post exposure prophylaxis

Protocol summary

Summary

This study is a double blind, randomized, clinical trial. The aims of this study is assessment of adverse local and systemic reactions of two approved rabies vaccine; purified chick embryo cell vaccine (PCEC) and purified vero cell rabies vaccine (VERO). Study populations include people bitten by animals from 8 different cities of Iran (Ghaemshahr, Sari, Gonbad, Aqqala, Gorgan, Kerman, Sirjan and Bam). Individuals will include in the study, if they are between 5 and 55 years of age and volunteer to participate in the study. They will exclude from the study if they have a history of previous animal bites; have received immunization against rabies previously; have a significant acute or chronic infectious disease; receiving transfusion with blood or blood products within the past month; are concomitantly receiving corticosteroids or immunosuppressive drug therapy; have axillary temperature 37.5°C before injection; or in the case of females, are pregnant. The study will started simultaneously at all healthcare centers and will be conducted for a period of one year from 2011 to 2012. Randomization will performed using the balanced block randomization; for 1:1 randomization of 2 groups and the blocks size of 4. Immediate systemic and local adverse reaction to the vaccines will monitored by the noninjecting physician within 30 minutes after each injection. Local and systemic reactions also, will be evaluated daily for 3 days after each injection by patients; and will be recorded on a special form.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015102124470N1**

Registration date: **2015-11-13, 1394/08/22**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2015-11-13, 1394/08/22

Registrant information

Name

Azra Ramezankhani

Name of organization / entity

Prevention of Metabolic Disorders Research Center,
Research Institute for Endocrine Science, Shahid

Country

Iran (Islamic Republic of)

Phone

+98 21 2243 2500

Email address

az.ramezankhani@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Center of Disease Control (CDC), Ministry of Health,
Tehran, Iran

Expected recruitment start date

2011-12-01, 1390/09/10

Expected recruitment end date

2012-12-01, 1391/09/11

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A comparative study on the adverse reactions of purified chick embryo cell vaccine (PCEC) and purified vero cell rabies vaccine (VERO) administered intramuscular as post exposure prophylaxis

Public title

Comparison of adverse reactions of two rabies vaccine

Purpose

Treatment

Inclusion/Exclusion criteria

inclusion criteria: age between 5 and 55 years; volunteer to participate in the study. exclusion criteria: have a history of previous animal bites; receiving immunization against rabies previously; have a significant acute or chronic infectious disease; receiving transfusion with blood or blood products within the past month; concomitantly receiving corticosteroids or immunosuppressive drug therapy; have axillary temperature 37.5°C before injection; being pregnant in females

Age

From **5 years** old to **55 years** old

Gender

Both

Phase

1-2

Groups that have been masked

No information

Sample size

Target sample size: **1800**

Randomization (investigator's opinion)

Randomized

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

Double blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

The committee of rabies control, Ministry of Health and Medical Education, Tehran, I. R. of Iran.

Street address

Eyvanak Blvd, Farahzadi Ave, Sanat Sq, Shahrake Qods (Gharb), Tehran, Iran.

City

Tehran

Postal code**Approval date**

2011-04-10, 1390/01/21

Ethics committee reference number

2011-4-3

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

Rabies

ICD-10 code

A82

ICD-10 code description

animal bites

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

Lymphadenopathy

Timepoint

30 minutes after each injection

Method of measurement

By physician

2**Description**

bruising

Timepoint

30 minutes after each injection

Method of measurement

By physician

3**Description**

itching

Timepoint

30 minutes after each injection

Method of measurement

By physician

4**Description**

abscesses

Timepoint

30 minutes after each injection

Method of measurement

b

5**Description**

erythema

Timepoint

30 minutes after each injection

Method of measurement

By physician

6**Description**

swelling

Timepoint

30 minutes after each injection

Method of measurement

By physician

Secondary outcomes

1

Description

dizziness

Timepoint

3 day after each injection

Method of measurement

evaluate by the patirnt

2

Description

stomach ache

Timepoint

3 day after each injection

Method of measurement

evaluate by the patirnt

3

Description

nausea

Timepoint

3 day after each injection

Method of measurement

evaluate by the patirnt

4

Description

weakness

Timepoint

3 day after each injection

Method of measurement

evaluate by the patirnt

5

Description

muscle aches

Timepoint

3 day after each injection

Method of measurement

evaluate by the patirnt

6

Description

fever

Timepoint

3 days after each injection

Method of measurement

evaluated daily by patients

7

Description

vomiting

Timepoint

3 day after each injection

Method of measurement

evaluate by the patirnt

Intervention groups

1

Description

In intervention group PCEC will be administered with 5 doses on days 0, 3, 7, 14, and 28, in animal bite subjects, who are classified in the second group (emergency vaccination) and third (routine vaccination against rabies serum) according to the World Health Organization's classification.

Category

Treatment - Drugs

2

Description

In control group Vero will be administered with 5 doses on days 0, 3, 7, 14, and 28, in animal bite subjects, who are classified in the second group (emergency vaccination) and third (routine vaccination against rabies serum) according to the World Health Organization's classification.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Healthcare center of Sari

Full name of responsible person

Ali Estar Abadi

Street address

Amir Mazandarani St, Shahband St, Sari, Iran

City

Sari

2

Recruitment center

Name of recruitment center

Healthcare center of Ghaemshahr

Full name of responsible person

Mohammad Ibrahim Saeed Poor

Street address

Alborz 66 St, Ayatollah Salehi mazandarani, Ghaemshahr, Iran

City

Ghaemshahr

3

Recruitment center

Name of recruitment center
Gonbad-e Qabus Health center
Full name of responsible person
Abdul Ghayom Karimi
Street address
Sarabi St, Gonbad-e Qabus, Iran
City
Gonbad

4

Recruitment center
Name of recruitment center
Healthcare center of Aqqala
Full name of responsible person
Street address
Abdul Rahman Shirmohammadli
City
Aqqala

5

Recruitment center
Name of recruitment center
Qom Health Center
Full name of responsible person
Mohammad Elmi Fard
Street address
Bist Metri Shahid Beheshti, Qom, Iran
City
Qom

6

Recruitment center
Name of recruitment center
Healthcare center of Kerman
Full name of responsible person
Azar Haji mahani
Street address
Shbanyh Cross, 22 Bahman Blvd, Khajoye Kermani
Sq, Kerman, Iran
City
Kerman

7

Recruitment center
Name of recruitment center
Healthcare center of Sirjan
Full name of responsible person
Gholam Hossein Tajabadi Pour
Street address
Alley Zendane Ghadim, Takhti St, Sirjan, Iran
City
Sirjan

8

Recruitment center
Name of recruitment center
Healthcare center of Bam
Full name of responsible person

Mojtaba Darijani
Street address
Next to the central laboratory, Nohsad meteri St,
Imam Blvd, Bam, Iran
City
Bam

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Center of Disease Control (CDC), Ministry of Health,
Tehran, Iran
Full name of responsible person
Mahmood Nabavi
Street address
Center of Disease Control (CDC), Ministry of Health,
Tehran, Iran
City
Tehran
Grant name
Grant code / Reference number
**Is the source of funding the same sponsor
organization/entity?**
Yes
Title of funding source
Center of Disease Control (CDC), Ministry of Health,
Tehran, Iran
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
Center of Disease Control (CDC), Ministry of Health,
Tehran, Iran
Full name of responsible person
Roghieh Ramezankhani
Position
expert/MS
Other areas of specialty/work
Street address
Eyvanak Blvd, Farahzadi Ave, Sanat Sq, Shahrake
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Web page address**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Center of Disease Control (CDC), Ministry of Health,
Tehran, Iran

Full name of responsible person

Mohammad Reza Shirzadi

Position

MD

Other areas of specialty/work**Street address**

Eyvanak Blvd, Farahzadi Ave, Sanat Sq, Shahrake
Qods (Gharb), Tehran, Iran.

City

Tehran

Postal code**Phone**

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Fax**Email**

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Web page address**Person responsible for updating data****Contact****Name of organization / entity**

Prevention of Metabolic Disorders Research Center,
Research Institute for Endocrine Science, Shahid

Full name of responsible person

Azra Ramezankhani

Position

Researcher/PhD

Other areas of specialty/work**Street address**

No.24, Shahid Arabi St, Yemen Blvd, Chamran Exp,
Tehran, Iran.

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1985711151

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Fax**Email**

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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