Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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

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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
ittching
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
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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
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Web page address

Person responsible for updating data

Contact
Name of organization / entity
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Full name of responsible person
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ma.ramezankhani@gmail.com
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