# Clinical trial comparing two medicines for the treatment of verruga Peruana

Submission date	Recruitment status  No longer recruiting	<ul><li>Prospectively registered</li></ul>		
21/01/2016		☐ Protocol		
Registration date 11/03/2016 Last Edited	Overall study status Completed Condition category	Statistical analysis plan		
		Results		
		Individual participant data		
25/04/2023	Infections and Infestations	<ul><li>Record updated in last year</li></ul>		

#### Plain English summary of protocol

Background and study aims

Bartonellosis, also known as Carrión's disease, is an infectious disease caused by the bacteria Bartonella bacilliformis. It is very common in the Andes mountain range, particularly in Peru, and is spread through the bites of sand flies. The infection usually takes part in two distinct phases. The first stage is known as Oroya fever, which is potentially life-threatening as red blood cells are destroyed so the body is unable to carry enough oxygen around the body (haemolytic anaemia). The second stage is the verrucous stage (verruga peruana, also known as the Peruvian wart) and involves long-term (chronic) skin lesions (wounds) on the limbs and face. They can last for months or even years, and are often accompanied by fever, tiredness and muscle pain. The infection mainly affects children, as their immune systems are still developing and they have not had time to become resistant through long-term exposure to the disease. One the verrucous stage clears up, most people are free from infection, however some people are still infected and can pass on the disease, even if they don't have any symptoms. Two common drugs used to treat people in the verrucous stage are azithromycin and rifampin, however it is not known whether one is more effective than the other. The aim of this study is to find out whether azithromycin or rifampin is faster at clearing up Bartonellosis in the verrucous stage.

## Who can participate?

Anyone who is showing signs of a long term Bartonellosis in the verrucous stage.

# What does the study involve?

Participants are randomly allocated to one of two groups. Those in the first group are given rifampin treatment for two weeks, at a dose of 600mg tablets daily for participants over 8 years old and 10mg/kg daily of liquid medication for children under 8 years old. Those in the second group are treated with azithromycin a week for two weeks, at a dose of 1g for participants over 8 years old and 20mg/kg for children under 8 years old. Participants in both groups have blood samples taken at the start of the study and then again on day 7, 14, 40 and 60 in order to test the effectiveness of the medications. At these times, participants are also examined physically in order to see if their skin lesions have improved.

What are the possible benefits and risks of participating?

Participants could benefit from an improvement to their symptoms from the medications used

in this study. There is a small risk of pain, bruising or infection from blood tests involved, as well as general side-effects associated with the medications used.

Where is the study run from? Caraz Regional Hospital (Peru)

When is the study starting and how long is it expected to run for? June 2003 to March 2004

Who is funding the study?

- 1. Uniformed Services University of the Health Sciences (USA)
- 2. Pfizer (USA)

Who is the main contact? Dr David Blazes david.blazes@usuhs.edu

# **Contact information**

#### Type(s)

Scientific

#### Contact name

Dr David Blazes

#### Contact details

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# Additional identifiers

#### Protocol serial number

G187OG-01

# Study information

#### Scientific Title

A randomized controlled treatment trial for the verrucous stage of Bartonella bacilliformis infection in Peru

## **Study objectives**

Thaim of this study is to determine the more efficacious drug for the treatment of the verrucous stage of Bartonella bacilliformis infection via a randomized, controlled trial, comparing azithromycin with rifampin.

#### **Null Hypotheses:**

- 1. There is no difference between azithromycin and rifampin treatment in the time to resolution of the verrucous rash of Bartonella bacilliformis infection
- 2. There is no difference between azithromycin and rifampin treatment in the duration of Bartonella bacilliformis bacteremia associated with the verrucous rash

#### Ethics approval required

Old ethics approval format

#### Ethics approval(s)

- 1. Naval Medical Research Center, 28/06/2001, ref: FWA-00000152
- 2. Services University of the Health Sciences, 12/04/2001, ref: FWA-00001628
- 3. Peruvian University Cayetano Heredia, 04/09/2001, ref: FWA-00000525

#### Study design

Community-based randomised parallel trial

#### Primary study design

Interventional

# Study type(s)

Treatment

## Health condition(s) or problem(s) studied

Bartonella bacilliformis infection

#### **Interventions**

Participants are randomly allocated to one of two groups using random computer generation of a scheme, blocked in groups of ten to ensure similar numbers will be assigned to each group.

Group 1: Adult participants receive Rifamin for two weeks at a dose of 600mg PO daily, Ch receild participants receive 10mg/kg daily (not to exceeding 600mg PO daily).

Group 2: Azithromycin .s administered once weekly for two weeks (which gives effective tissue levels for two weeks). Adults receive a 1.0 gram PO dose at Day 0 and Day 8 and children receive a 20mg/kg PO dose at Day 0 and Day 8 (not to exceed standard adult doses as above).

For both groups, liquid elixirs are provided for children less than eight years of age, with tablets for all patients older than eight years.

Participants in both groups are followed up after 7, 14, 30 and 60 days.

#### Intervention Type

Drug

#### Phase

Phase III/IV

# Drug/device/biological/vaccine name(s)

1. Rifampin 2. Azithromycin

#### Primary outcome(s)

- 1. Time to resolution of verrucous lesions is measured from photographs and physical examinations undertaken at baseline, 7, 14, 30 and 60 days
- 2. Time to resolution of Bartonella bacteremia is measured through blood culture and PCR undertaken at baseline, 7, 14, 30 and 60 days

## Key secondary outcome(s))

- 1. Risk factors for Bartonella bacteremia measured using a questionnaire at baseline
- 2. Characteristics for clinical and laboratory findings associated with rash and Bartonella bacteremia measured at baseline, 7, 14, 30 and 60 days

#### Completion date

30/03/2004

# Eligibility

#### Key inclusion criteria

- 1. Aged between 1 and 60 years
- 2. Clinical presentation compatible with Verruga peruana (chronic verrucous stage of Bartonellosis)
- 3. Able to provide informed consent/parental informed consent for children

#### Participant type(s)

Patient

## Healthy volunteers allowed

No

## Age group

Mixed

#### Sex

Αll

# Key exclusion criteria

- 1. Pregnancy
- 2. Use of oral contraceptives
- 3. Breast-feeding
- 4. Admission to the hospital for an unrelated condition
- 5. Use of antibiotics within the month preceding potential enrollment in the trial
- 6. Chronic use of alcohol
- 7. Known chronic liver disease
- 8. Use of medications that potentially interact with rifampin or azithromycin during the study period

#### Date of first enrolment

16/06/2003

#### Date of final enrolment

15/12/2003

# Locations

#### Countries of recruitment

Peru

Study participating centre Caraz Regional Hospital

9 de octubre Av S/N Caraz

Huaylas Ancash

Peru

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# Sponsor information

#### Organisation

Uniformed Services University of the Health Sciences

#### **ROR**

https://ror.org/04r3kq386

# Funder(s)

## Funder type

Government

#### **Funder Name**

Uniformed Services University of the Health Sciences

# Alternative Name(s)

Uniformed Services University, USU of the Health Science, Uniformed Services University of Health Sciences, The Uniformed Services University of the Health Sciences, USUHS, USU

#### Funding Body Type

Government organisation

# **Funding Body Subtype**

National government

#### Location

#### **Funder Name**

Pfizer

#### Alternative Name(s)

Pfizer Inc., Pfizer Consumer Healthcare, Davis, Charles Pfizer & Company, Warner-Lambert, King Pharmaceuticals, Wyeth Pharmaceuticals, Seagen, Pfizer Inc

#### **Funding Body Type**

Government organisation

# **Funding Body Subtype**

For-profit companies (industry)

#### Location

United States of America

# **Results and Publications**

# Individual participant data (IPD) sharing plan

Not provided at time of registration

# IPD sharing plan summary

Available on request

# **Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient- facing?
Other publications	Whole-Genome Analysis of Bartonella ancashensis,	01/03 /2017	25/04 /2023	Yes	No
Participant information sheet	Participant information sheet	11/11 /2025	11/11 /2025	No	Yes