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Clinical trial comparing two medicines for the treatment of verruga Peruana

Submission date
21/01/2016

Recruitment status
No longer recruiting

Registration date
11/03/2016

Overall study status
Completed

Last Edited
25/04/2023

Condition category
Infections and Infestations

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

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
Dept of Tropical Public Health
Uniformed Services University of the Health Sciences
4301 Jones Bridge Road
Bethesda
United States of America
20814
+1 202 957 4446
david.blazes@usuhs.edu

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised parallel trial

Study setting(s)
Community

Study type(s)
Treatment

Participant information sheet
No specific participant information sheet available, please use the contact details below to request a further information.

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 measure
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

Secondary outcome measures
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

Overall study start date
16/06/2003

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

Age group
Mixed

Sex

Both

Target number of participants
127

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

Sponsor details
4301 Jones Bridge Road
Bethesda
United States of America

20814
+1 301 295 3734
james.mancuso@usuhs.edu

Sponsor type
University/education

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
United States of America

Funder Name
Pfizer

Alternative Name(s)
Pfizer Inc., Pfizer Consumer Healthcare, Davis, Charles Pfizer & Company, Warner-Lambert, King Pharmaceuticals, Wyeth Pharmaceuticals, Seagen

Funding Body Type
Government organisation

Funding Body Subtype
For-profit companies (industry)

Location

United States of America

Results and Publications

Publication and dissemination plan
Planned publication of results papers in peer reviewed journals. The clinical trial data has also been presented at the ASTMH meeting in Philadelphia in November 2015.

Intention to publish date
01/06/2016

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