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A research study to measure RO7223280 levels in participants who have bacterial infections causing severe illness

Submission date
21/06/2022

Recruitment status
No longer recruiting

Registration date
22/06/2022

Overall study status
Completed

Last Edited
04/12/2023

Condition category
Infections and Infestations

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

Plain English summary of protocol

Background and study aims
Nosocomial bacterial pneumonia is an infection of the lungs. Bacteraemia is an infection of the blood. Both are severe invasive infections caused by bacteria. The drug under study (RO7223280) is being developed for the possible treatment of such infections. RO7223280 is an experimental drug i.e., the Health Authorities (like the U.S Food and Drug Administration and European Medicines Agency) have not approved RO7223280 for the treatment of infections.
The main purpose of this study is: -
1. To measure the drug levels in the body
2. To determine the safety of the drug

Who can participate?
Patients who are aged 18 years old and over and are critically ill because of hospital-acquired bacterial pneumonia (HABP), ventilator-associated bacterial pneumonia (VABP), or bacteraemia.

What does the study involve?
The maximum length of participation in the study is about 9 days.
The study will include:
1. Screening period: The screening period will last up to 5 days. All participants will be screened to make sure they are a good fit for the study.
2. Treatment period: All participants will receive a single dose of 600 mg of RO7223280 over 1 hour through a needle put into a vein in the arm (infusion) on Day 1. The participants will have to stay in the hospital during the treatment. Some blood samples will be taken on Day 1.
3. Safety Follow-up Period: Additional blood samples will be taken on Days 2 and 3. Participants will have a check-up on Days 2 to 4 after the treatment period.

What are the possible benefits and risks of participating?
Participants may not receive any health benefits from participating in this study, but the information learned in this study may help patients with similar conditions in the future.
Participants may experience side effects from the study drug, and these can be mild to severe and can vary from person to person. RO7223280 has had limited testing in humans. The known

side effects of this drug, as well as potential side effects, are listed below. There may potentially also be side effects that are not known at this time.
1. Itching
2. Flushing
3. Shortness of breath
4. Headache
5. Skin inflammation
6. Skin bruising

There may be a risk in exposing an unborn child to the study drug, and all risks are not known at this time. Women and men must take precautions to avoid exposing an unborn child to the study drug. Participants who are pregnant, become pregnant, or are currently breastfeeding cannot take part in this study.

Where is the study run from?
F. Hoffmann-La Roche Ltd (USA)

When is the study starting and how long is it expected to run for?
December 2021 to December 2023

Who is funding the study?
F. Hoffmann-La Roche Ltd (USA)

Who is the main contact?
global-roche-genentech-trials@gene.com

Contact information

Type(s)
Public

Contact name
Dr Clinical Trials

Contact details
1 DNA Way
South San Francisco
United States of America
94080
+1 888-662-6728
global-roche-genentech-trials@gene.com

Additional identifiers

ClinicalTrials.gov (NCT)
NCT05614895

Clinical Trials Information System (CTIS)
2022-000456-11

Protocol serial number
BP43949

Study information

Scientific Title
A multicenter, single-dose, uncontrolled, open-label, one group study to investigate the pharmacokinetics of RO7223280 in critically ill patients with bacterial infections

Study objectives
The main aim of the study is to investigate the plasma pharmacokinetic (PK) and safety of intravenous (IV) administration of a single dose of 600 mg RO7223280 in critically ill participants with bacterial infections

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 06/05/2022, WCG IRB (1019 39th Avenue, SE Suite 120 Puyallup, WA 98374, USA; +1 855 818 2289; clientservices@wcgirb.com), ref: 1-1540488-1

Primary study design
Interventional

Study design
Multicentre single-dose uncontrolled open-label phase Ib study

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Bacterial Infections

Interventions
1. Cohort A - Bacteraemia participants without pneumonia and who are not mechanically ventilated at screening will be enrolled in this cohort. Participants will receive RO7223280, 600 mg, IV infusion for 1 hour on Day 1.
2. Cohort B – Participants with hospital-acquired bacterial pneumonia (HABP) and who are not mechanically ventilated at screening will be enrolled in this cohort. Participants will receive RO7223280, 600 mg, IV infusion for 1 hour on Day 1.
3. Cohort C – Participants with mechanical ventilation at screening will be enrolled in this cohort. Participants will receive RO7223280, 600 mg, IV infusion for 1 hour on Day 1.

Intervention Type
Drug

Phase
Phase I

Drug/device/biological/vaccine name(s)

RO7223280

Primary outcome(s)
1. Maximum plasma concentration (Cmax) of RO7223280 measured using plasma samples at multiple timepoints from day 1 to day 3
2. Time to maximum observed concentration (Tmax) of RO7223280 measured using plasma samples at multiple timepoints from day 1 to day 3
3. Observed plasma concentration (Cend) at the end of infusion of RO7223280 measured using plasma samples at day 1
4. Area under the concentration- time curve from time zero to the last measurable concentration (AUClast) of RO7223280 measured using plasma samples at multiple timepoints from day 1 to day 3
5. Area under the concentration- time curve extrapolated to infinity (AUC0-∞) of RO7223280 measured using plasma samples at multiple timepoints from day 1 to day 3
6. Apparent terminal elimination half-life (T1/2) of RO7223280 measured using plasma samples at multiple timepoints from day 1 to day 3
7. Terminal rate constant (λz) of RO7223280 measured using plasma samples at multiple timepoints from day 1 to day 3
8. Total body clearance (CL) of RO7223280 measured using plasma samples at multiple timepoints from day 1 to day 3
9. Volume of distribution at steady state (Vss) of RO7223280 measured using plasma samples at multiple timepoints from day 1 to day 3

Key secondary outcome(s)
1. Percentage of participants with adverse events (AEs) from screening to follow up period (from day 1 up to day 4)
2. Percentage of participants with serious adverse events (SAEs) from screening to follow up period (from day 1 up to day 4)
3. Percentage of participants who died due to any cause from screening to follow up period (from day 1 up to day 4)

Completion date
31/12/2023

Eligibility

Key inclusion criteria
1. Aged 18 years old and over
2. Illness requiring treatment in an intensive care unit (ICU) at the time of enrolment
3. Ongoing clinical syndrome meeting at least one of the following criteria:
3.1. HABP: bacterial pneumonia diagnosed after more than 48 hours of hospitalization or within 7 days after a hospital discharge
3.2. Ventilator-associated bacterial pneumonia (VABP): bacterial pneumonia diagnosed after more than 48 hours of mechanical ventilation or within 72 hours after weaning
3.3. Bacteraemia confirmed by the presence of a bacterial pathogen in a blood culture drawn within 7 days prior to dosing and with the defined focus of infection.

Participant type(s)
Patient

Healthy volunteers allowed

No

Age group
Adult

Lower age limit
18 Years

Sex
All

Key exclusion criteria
1. Ongoing documented catheter-related bacteraemia as the sole ongoing infection
2. Major surgery within 48 hours prior to dosing or major surgery expected within 48 hours after the start of the infusion
3. Known chronic severe hepatic impairment (Child-Pugh class C). Note: acute severe hepatic impairment is not exclusionary

Date of first enrolment
30/06/2022

Date of final enrolment
22/12/2023

Locations

Countries of recruitment
Brazil

France

Israel

Korea, South

United States of America

Study participating centre
Instituto de Moléstias Cardiovasculares Tatuí
R. Cel. Aureliano de Camargo
905 - Centro
Tatuí
Brazil
18270-170

Study participating centre

Hospital de Clínicas de Porto Alegre
Porto Alegre
Brazil
90035-903

Study participating centre
Fundação Bahiana de Infectologia
R. João das Botas
185 - Garcia
Salvador
Brazil
40110-160

Study participating centre
Nucleo de Ensino e Pesquisas Mario Penna - Instituto Mario Penna
R. Joaquim Cândido Filho
91 - Luxemburgo
Belo Horizonte
Brazil
30380-420

Study participating centre
Hôpitaux Universitaires de strasbourg - hôpital civil
Strasbourg
France
67000

Study participating centre
CHU de Limoges - Hôpital Dupuytren
Limoges
France
87042

Study participating centre
Hôpital Saint-Louis
Paris
France
75015

Study participating centre
Groupe Hospitalier Bichat Claude Bernard
Paris
France
75018

Study participating centre
Centre Hospitalier Régional Universitaire de Lille
Lille
France
59037

Study participating centre
Ziv Medical Center
Safed
Israel
13100

Study participating centre
Galilee Medical Center
Nahariya
Israel
2210001

Study participating centre
The Chaim Sheba Medical Center
Multiple Sclerosis Center
Tel HaShomer
Israel
5266202

Study participating centre
Tel-Aviv Sourasky Medical Center
Tel Aviv
Israel
6423906

Study participating centre

Hadassah Ein Karem Hospital
Jerusalem
Israel
91120

Study participating centre
Asan Medical Center
Seoul
Korea, South
138-736

Study participating centre
Hallym University Kangnam Sacred Heart Hospital
Seoul
Korea, South
07441

Study participating centre
Oregon Health & Science University
Oregon
United States of America
97239

Study participating centre
Beaumont Hospital
Royal Oak Pharmacy
Royal Oak
United States of America
48073-6712

Study participating centre
East Carolina University (ECU) Physicians
Infectious Disease Clinic
Greenville
United States of America
27858

Study participating centre

Henry Ford Hospital
Detroit
United States of America
48202-2608

Study participating centre
University of Louisville Physicians
Louisville
United States of America
40202-5703

Study participating centre
Infectious Disease Associates
Toledo
United States of America
43608

Sponsor information

Organisation
F. Hoffmann-La Roche Ltd

Funder(s)

Funder type
Industry

Funder Name
F. Hoffmann-La Roche

Alternative Name(s)
Hoffman-La Roche, F. Hoffmann-La Roche Ltd.

Funding Body Type
Private sector organisation

Funding Body Subtype
For-profit companies (industry)

Location

Switzerland

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are not expected to be made available due to participant-level data not being a regulatory requirement

IPD sharing plan summary
Not expected to be made available