

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

<b>Submission date</b> 21/06/2022	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered
<b>Registration date</b> 22/06/2022	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 04/12/2023	<b>Condition category</b> Infections and Infestations	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> 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

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South San Francisco

United States of America

94080

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global-roche-genentech-trials@gene.com

## Additional identifiers

### Clinical Trials Information System (CTIS)

2022-000456-11

### ClinicalTrials.gov (NCT)

NCT05614895

**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

**Study design**

Multicentre single-dose uncontrolled open-label phase Ib study

**Primary study design**

Interventional

**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 (C<sub>max</sub>) of RO7223280 measured using plasma samples at multiple timepoints from day 1 to day 3
2. Time to maximum observed concentration (T<sub>max</sub>) of RO7223280 measured using plasma samples at multiple timepoints from day 1 to day 3
3. Observed plasma concentration (C<sub>end</sub>) 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 (AUC<sub>last</sub>) 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 (AUC<sub>0-∞</sub>) of RO7223280 measured using plasma samples at multiple timepoints from day 1 to day 3
6. Apparent terminal elimination half-life (T<sub>1/2</sub>) of RO7223280 measured using plasma samples at multiple timepoints from day 1 to day 3
7. Terminal rate constant (λ<sub>z</sub>) 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 (V<sub>ss</sub>) 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