ForPatients
*by Roche*

Healthy Volunteers

# Open-label, non-randomized study investigating the excretion balance, pharmacokinetics, and metabolism of a single intravenous dose of [14C]-labelled RO7223280 in healthy male participants

| Trial Status | Trial Runs In | Trial Identifier |
|---|---|---|
| Recruiting | 1 Countries | BP43532 |

*The source of the below information is the publicly available website ClinicalTrials.gov. It has been summarised and edited into simpler language.*

## *Trial Summary:*

A study in healthy males to assess how the radiolabelled test medicine RO7223280 is broken down, processed and removed from the body

**F. Hoffmann-La Roche Ltd (USA)**
Sponsor

**Phase 1**
Phase

**BP43532**
Trial Identifiers

## *Eligibility Criteria:*

| Gender | Age | Healthy Volunteers |
|---|---|---|
| Male | Adult | Yes |

### Background and study aims:

Antibiotics are medicines used to prevent and treat bacterial infections. Antibiotic resistance occurs when bacteria adapt and change in response to the use of these medicines in such a way that medicines can no longer kill them. One of the bacterial strains which has resistance to multiple antibiotics is Acinetobacter baumannii. This bacteria type is most commonly found in hospitals leading to hospital-acquired bacterial infections in people with a compromised immune system.

The aim of this study is to test the study drug (RO7223280) designed for the treatment of hospital-acquired (or nosocomial) bacterial pneumonia (HABP), ventilator-associated bacterial pneumonia (VABP), and bloodstream infections (BSI) caused by A. baumannii. The study looks to see how quickly and to what extent RO7223280 is distributed, broken down (metabolized), and eliminated from the human body (pharmacokinetics). For this

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study, RO7223280 is radioactively labelled with carbon-14 (14C). In this way, RO7223280 can be traced in blood, plasma, urine, and faeces.

**Who can participate?**

Healthy male volunteers aged between 35 to 64 years old

**What does the study involve?**

Once enrolled, participants will need to be a part of this study for up to 22 days. This study will have three parts:

1. A screening period of 28 days, where certain tests would be done to determine if the participant is eligible to take part in the study

2. A treatment period, where eligible participants will be enrolled and will receive a single 1-hour infusion into the vein (intravenous) of 14C-labelled-RO7223280 on Day 1 in the research centre. Participants will be required to stay in the research centre for a period of at least 16 days (15 nights). The stay might be extended to 22 days if a participant has not passed at least 95% of radioactivity out of their bodies.

3. A follow-up period during which participants will have to return to the research centre at approximately 7 days after the last urine and faeces samples are collected

**What are the possible benefits and risks of participating?**

Participants will receive monetary compensation of €4021 for participation in the entire study. Reserve participants (individuals who are approved for screening but do not take part in the study) will receive a compensation of €529. The information gained from this study may help investigators to increase their knowledge about the effects of RO7223280 and help in the search for better treatment of bacterial infections.

Participants may have side effects from the drug RO7223280. These can be mild to severe and even life-threatening, and they can vary from person to person.

The potential side effects associated with RO7223280 or study procedures are listed below:

Risks associated with RO7223280:

RO7223280 might have (serious) side effects that are still unknown. In addition to unknown side effects, there is a (small) chance that an allergic reaction will occur. This can be caused by the study compound or other ingredients that are used to prepare the formulation. The most common side effects observed previously were infusion-related

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effects such as itching, flushing, shortness of breath etc. Other side effects include headache and, skin inflammation, and skin bruising caused by infusion needles.

Coronavirus test:

Samples for the coronavirus test will be taken from the back of the participant’s nose and throat using swabs. Taking the samples can cause discomfort and can give an unpleasant feeling. Taking a sample from the back of the throat may cause the participant to gag. When the sample is taken from the back of the nose, the participant may experience a stinging sensation and the eyes may become watery.

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