ForPatients
by Roche

Spinal Muscular Atrophy (SMA)

A clinical trial to look at how safe risdiplam is and how well risdiplam is processed by the body in healthy volunteers. The trial will also test how risdiplam affects the way that the body processes midazolam.

A Drug-drug Interaction Study With Risdiplam Multiple Dose and Midazolam in Healthy Participants

Trial Status	Trial Runs In	Trial Identifier
Completed	1 Countries	NCT03988907 BP41361

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

Trial Summary:

This will be a Phase I, 2-part, open-label, non-randomized study to investigate the safety, tolerability, and pharmacokinetics (PK) of a multiple-dosing regimen of risdiplam (Part 1) and the effect of risdiplam on the PK of midazolam (Part 2) following oral administration in healthy adult male and female participants.

Hoffmann-La Roche Sponsor	**Phase 1** Phase

NCT03988907 BP41361
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
All	>=18 Years & <= 55 Years	Accepts Healthy Volunteers

How does the BP41361 clinical trial work?

This clinical trial is recruiting healthy volunteers.

The purpose of this clinical trial is to test the safety of risdiplam and to understand the way your body processes risdiplam. It will also test whether risdiplam affects the way your body processes another drug called midazolam.

How do I take part in this clinical trial?

To be able to take part in this clinical trial, you must be aged between 18 and 55 and be classed as healthy by the clinical study doctors.

You must not have taken part in any other clinical trials within the last 3 months and you will not be able to take part in the trial if you are a woman who is able to have children.

If you think this clinical trial may be suitable for you and would like to take part, please talk to your doctor. If your doctor thinks that you might be able to take part in this clinical trial, he/she may refer you to the closest clinical trial doctor. They will give you all the information you need to make your decision about taking part in the clinical trial. You can also find the clinical trial locations on this page.

You will have some further tests to make sure you will be able to take the treatments given in this clinical trial.

Before starting the clinical trial, you will be told about any risks and benefits of taking part in the trial.

While taking part in the clinical trial, men will need to either not have heterosexual intercourse or take contraceptive medication for safety reasons.

What treatment will I be given if I join this clinical trial?
The clinical trial will be split into 2 parts. If you join Part 1 of the clinical trial, you will not be able to join Part 2.

Part 1 The purpose of Part 1 will be to confirm that risdiplam is safe and confirm the best dose of risdiplam. Everyone who joins Part 1 will be given risdiplam as a liquid to drink every day for 14 days.

If you join Part 1, you will have to stay in the clinic for 18 days and then visit the clinic 2 days and 4 days after you finish your stay.

Once risdiplam has been confirmed as safe and the best dose has been selected based on the data from Part 1, the trial will move on to Part 2.

Part 2 Part 2 will test whether risdiplam affects how the body processes midazolam. Everyone who joins Part 2 will be given risdiplam as a liquid to drink every day for 14 days (starting on Day 5 of your clinic stay) and midazolam as liquid to drink on Day 3 and Day 17 of your clinic stay.

If you join Part 2, you will have to stay in the clinic for 20 days and then visit the clinic 2 days and 4 days after you finish your stay.

How often will I be seen in follow-up appointments, and for how long?

You will be given the clinical trial treatment risdiplam OR risdiplam and midazolam for about 2 weeks. You are free to stop this treatment at any time. You will be seen by the clinical trial doctor 10 days after your last treatment. This is to see how you are responding to the treatment and any side effects that you may be having.

What happens if i am unable to take part in this clinical trial?
If this clinical trial is not suitable for you, you will not be able to take part.

For more information about this clinical trial see the **For Expert** tab on the specific ForPatient page or follow this link to ClinicalTrials.gov

Trial-identifier: NCT03988907