The POINT-HD Study

POINT-HD is an early stage (Phase 1) clinical study sponsored by Roche, a global pharmaceutical company, that has been researching treatments for Huntington's disease (HD) for more than a decade. This study is testing an investigational (not yet approved) drug called RG6496. The goal is to see if disease progression can be slowed down in people living with HD, by targeting just the faulty protein that causes the disease.

Why is this study needed?

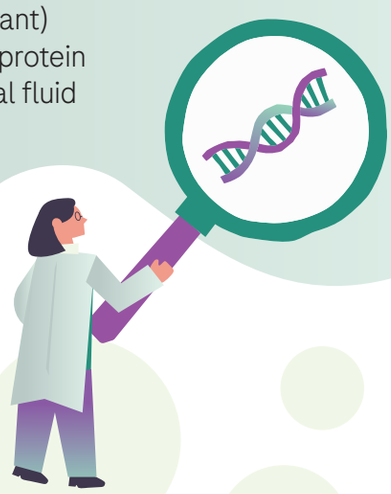
HD is a progressive condition that has a profound impact on individuals and their families. There is an urgent need for new and effective treatments to slow down disease progression.

RG6496 is being developed to specifically lower levels of the faulty huntingtin protein, while keeping healthy huntingtin protein. It works by targeting a specific genetic variation that some people carry in their HD gene.

This is the first time RG6496 will be tested in people. Phase 1 studies are important early steps in research – they help determine how a drug behaves in the body, how much can be safely given and whether there are side effects. What we learn here will also help guide future studies.

What are the main aims of the POINT-HD study?

- To understand how safe RG6496 is at different doses
- To study how the drug moves through and leaves the body
- To measure levels of the faulty (mutant) huntingtin protein in the spinal fluid



What kind of support will I receive?

- A dedicated study team will support you throughout the study and procedures, and answer any questions
- You will be provided or reimbursed for study support services such as travel, accommodation, meals and time (where allowed by local laws)
- Your privacy will be protected according to all applicable laws and regulations

What are the risks or benefits?

- The POINT-HD study is the first time RG6496 will be tested in humans, but it has been studied in animal laboratory tests
- There are potential risks associated with the investigational drug and the lumbar puncture procedure, which will be discussed with you in detail before you decide whether to join the study
- Detailed information about the study, risks and benefits will be provided in an informed consent document
- Taking part may not directly improve your health, but the information gathered can help future research on HD

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Who can take part in this study?

You may be able to take part if you:

- Are 25–65 years old
- Have early or mild HD symptoms
- Carry a specific genetic variation in the HD gene targeted by RG6496

The doctor leading the study will check all criteria to confirm if this study is suitable for you.

What will this study involve?

- The study has two parts and lasts about two years. You must complete Part 1 before entering Part 2
- Dosing is given as a single injection via a procedure called a lumbar puncture or spinal tap
- The study involves one clinic visit with an overnight stay, monthly check-ups and completing digital tasks on a study-provided smartphone

Screening period

Up to 3 months

Before officially enrolling in the study, tests and health checks will occur to see if the study is a good fit for you.

Part 1: Treatment & follow-up period

About 7 months

You will be randomly assigned to receive a single dose of either RG6496 or a placebo (an inactive substance), followed by regular monitoring.

Part 2: Open-Label Extension (OLE)

About 13 months

You will receive a single dose of RG6496, followed by regular monitoring. For those who received RG6496 in Part 1, this will be the second time that they receive the study drug. For those who received placebo in Part 1, this will be the first time that they receive the study drug.

Interested in taking part?

Before starting the study, you'll receive a detailed study brochure and be asked to sign an informed consent form. Once enrolled in the study, you can choose to stop the study at any time – and your regular medical care will not be affected.

Thank you for your interest in POINT-HD. To learn more, please speak with your doctor or contact the study team.

PLACEHOLDER

Roche is grateful to the HD patient organisations and advisors who reviewed the POINT-HD study and provided valuable feedback that helped improve the study design and materials.

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