



Trial Information

Simple trial name: A clinical trial to see how safe and well-tolerated knee injections of RTX-GRT7039 are in people with knee pain caused by osteoarthritis.

Protocol number: KF7039-03

Trial Sponsor: Grünenthal GmbH

Thank you to the trial participants



If you took part in the clinical trial, thank you for your time and commitment.

You made the clinical trial possible.

You helped us on our way to bringing new medicines to patients.

Important note: This summary shares the results of a clinical trial. It is not intended to provide medical advice. If you have any questions about your health or treatment, please speak to your doctor.

About this summary

This summary is written to share the results of this clinical trial with the public. It is written in a way that should be easy for most people to understand. It describes why the trial was needed, how it was done, and the results.

1 General information about the clinical trial

Why was this trial needed?

Osteoarthritis (wear and tear of the joint) of the knee is a long-term condition that causes pain and limits movement. Many people with this condition still feel pain even when taking available treatments. Some patients also cannot take these treatments due to side effects or other health reasons.

All participants in this trial knew which treatment they were getting and had ongoing knee pain even though they were already receiving the best available treatment, or they couldn't take standard treatment because it wasn't suitable or caused side effects.

Which medicines were studied?



RTX-GRT7039: An experimental medicine containing the drug substance resiniferatoxin injected directly into the knee. It is designed to reduce pain by blocking nerve cells inside the joint. **RTX-GRT7039** has not been approved for use in humans.

What was the main objective of the trial?

The main objective of the trial was:

Are **RTX-GRT7039** injections safe and well-tolerated in people with knee pain due to osteoarthritis?

2 Duration of treatment?

Up to 78 weeks, including 1 injection on Day 1 and up to 5 injections in total, with at least 12 weeks apart between injections.

3 When and where did this trial take place?



This trial started on 15 August 2022 and ended on 15 May 2025.



The trial took place in 6 countries including Bulgaria, Japan, Poland, Romania, South Africa, and the United Kingdom.

4 Which participants were included in this trial?

- Adults aged 18 and older with knee osteoarthritis.
- All had moderate to severe pain in one or both knees.
- 714 participants received at least one injection of [RTX-GRT7039](#).

Which participants were able to take part in the trial?



Participants were only able to take part in the clinical trial if they met certain requirements. This was important to make sure that the trial participation was safe for each participant, and to make sure that the results of the clinical trial were valid, and the laws and regulations were followed.

Were the participants men or women?

Most of the participants were female:

- **Male:** 166 participants
- **Female:** 548 participants



5 What happened during this trial?

Each participant received an injection in the painful knee or both knees if both were affected. If pain continued or returned, participants could receive up to 4 more injections, in one or both knees, between 3 and 12 months after the first one, with at least 12 weeks between injections.

6 What were the overall results of this trial?

Safety:

- **RTX-GRT7039** was safe and well tolerated, including repeated injections.
- The number of side effects was similar between people who received injections in one knee and those who received injections in both knees.
- No new safety concerns were identified for **RTX-GRT7039**.
- There were no pregnancies.
- 4 participants died during the trial. All deaths were related to heart problems, none were caused by **RTX-GRT7039**.

7 What side effects did participants have in this trial?

Side effects are medical events that happened during the trial which the trial doctor and researchers need to investigate to know whether a medical event is related to **RTX-GRT7039** or not.

What serious side effects did the participants have?

- Serious side effects are those that may cause disability, lasting problems, life-threatening conditions, hospitalization, or death.
- 58 participants had serious side effects.
- Only 1 out of 70 serious side effects, that was loss of consciousness, was considered related to **RTX-GRT7039** and the injection procedure.



How many participants had non-serious side effects?

- 377 participants reported non-serious side effects.
- The most often reported side effects were due to pain from the injection procedure.
- No unusual results were found in blood tests, heart readings (ECG), vital signs (such as blood pressure), or X-ray results.

- 7 participants had changes in the structure of their knee joint, which were seen on scans, and only 1 out of 10 reported non-serious side effects was considered related to [RTX-GRT7039](#).

How many participants stopped the trial and treatment because of side effects?

- 9 participants stopped the trial because of side effects:
 - No specific side effect leading to stop the trial occurred in more than one participant.
 - None was caused by [RTX-GRT7039](#), local anesthetic, or injection procedure.
- 9 participants stopped receiving [RTX-GRT7039](#) because of side effects:
 - No specific side effect caused more than one participant to stop treatment, except for osteoarthritis, which led to hospital admission for knee replacement surgery in 5 participants.

How was this trial useful for patients and researchers?

This trial showed that the medicine was safe and tolerable when used as described. These findings may help guide future research into pain treatments for osteoarthritis of the knee.



If you have questions, please contact your trial doctor.

8 Where can I learn more about this trial?

EUCT number: [2024-515709-24-00](#)

US NCT number (*clinicaltrials.gov*): [NCT05377489](#)

WHO universal trial number (UTN): [U1111-1268-7230](#)

Full trial name: A single-arm, open label, Phase III trial to evaluate the safety and tolerability of intra-articular injections of RTX-GRT7039 in subjects with moderate to severe pain associated with osteoarthritis of the knee

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Date of summary: 30-October-2025