



Trial Information

Simple trial name: A clinical trial to test if a new treatment (1 injection) can reduce knee pain caused by osteoarthritis

Protocol number: KF7039-02

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 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.

This trial tested a new medicine, **RTX-GRT7039**, an injection into the knee joint, to find out if it helps reduce knee pain better than a **placebo** injection (a dummy treatment). The medicine is injected directly into the knee joint.

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.



Placebo (dummy treatment) looks like the test medicine (**RTX-GRT7039**) and is given in the same way but does not have any medicine in it. Researchers sometimes use a **placebo** to understand if the changes seen were due to the test medicine or were caused by other factors.

Other medication/treatment



Ropivacaine is an approved medicine and it is used in this trial as local painkiller injected directly into the knee joint 15 minutes before **RTX-GRT7039** or placebo to reduce pain during the procedure.

What was the main objective of the trial?

The main objective of the trial was:

Does **RTX-GRT7039** reduce knee pain better than placebo at 12 weeks after the first injection?

Researchers also wanted to know:

- If it continues to reduce pain and improve movement over a year, and
- If it is safe and well-tolerated.

2 Duration of treatment?

52 weeks, with 1 injection on Day 1.

3 When and where did this trial take place?



This trial started on 26 August 2022 and ended on 15 August 2024.



The trial took place in 4 countries including Denmark, Spain, United Kingdom, and United States.

4 Which participants were included in this trial?

- Adults aged 18 and older with knee osteoarthritis.
- All had moderate to severe pain in one knee for at least 6 months.
- 473 participants took part from 4 countries Denmark, Spain, United Kingdom, and United States.
- 231 received **RTX-GRT7039** and 235 received **placebo**.

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:** 159 participants
- **Female:** 307 participants



5 What happened during this trial?

Participants were randomly assigned to receive either **RTX-GRT7039** or **placebo** injections into one knee. They received:

- 1 injection on Day 1.
- Pain and movement were assessed regularly over a period of 52 weeks.

6 What were the overall results of this trial?

Efficacy:

- Both groups (**RTX-GRT7039** and **placebo**) showed improvement in pain and movement.
- However, the difference between groups was small and not statistically significant.
- This means **RTX-GRT7039** did not show additional benefit over **placebo**.

Safety:

- **RTX-GRT7039** was safe and well tolerated.
- A similar number of participants in the **RTX-GRT7039** group and in the **placebo** group had temporary side effects, whereas procedural pain (pain from the injection) occurred more often in the **RTX-GRT7039** group.
- No safety concerns were identified.
- There were no pregnancies or deaths during the trial.

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.
- Although 11 participants in the **RTX-GRT7039** group and 15 participants in the **placebo** group reported serious side effects, none was considered related to **RTX-GRT7039**.



How many participants had non-serious side effects?

- In this study, a similar number of participants who received **RTX-GRT7039** (111 participants) and who received **placebo** (118 participants) reported non-serious side effects.
- Most of these side effects in the **RTX-GRT7039** group 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.
- 2 participants had changes in the structure of their knee joint, which were seen on scans - 1 participant who received **RTX-GRT7039** and 1 participant who received **placebo**.

How many participants stopped the trial because of side effects?

- 2 participants in **RTX-GRT7039** group stopped trial participation due to side effects in this trial:
 - 1 participant reported osteoarthritis (wear and tear joint disease) and another participant reported atrial fibrillation (irregular heart rhythm [arrhythmia]).
- 6 participants in **placebo** group stopped trial participation due to side effects in this trial.
- The trial was completed as planned. When the trial ended, the sponsor reviewed the data and created a report of the results. This is a lay summary of that report.

How was this trial useful for patients and researchers?

Although **RTX-GRT7039** did not meet its main goal of showing better pain relief than placebo, the trial showed that the medicine was safe 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?

EudraCT identifier: [2021-005020-38](#)

US NCT number: [NCT05449132](#)

WHO universal trial number (UTN): [U1111-1268-7267](#)

Full trial name: A Randomized, Double-blind, Placebo-controlled, Phase III Trial, to Evaluate the Efficacy and Safety of a Single Intra-articular Injection of RTX-GRT7039 in Adult Subjects With Pain Associated With Osteoarthritis of the Knee

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