

Trial Information

Simple trial name: A study to learn how different doses of GRT6019 are tolerated in healthy men

Protocol number: HP6019-01

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: You should not use this summary to make decisions about the medical treatments you use. You should always see your doctor for advice about medical treatments.

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.

General information about the clinical trial

Why was this trial needed?

GRT6019 is a test medicine being developed to treat inflammatory conditions, which can cause swelling, fluid accumulation, and tissue damage. A standard treatment for these conditions is the use of steroids. However, steroids can cause unwanted or harmful reactions when used long-term. **GRT6019** works in a way that the researchers think will cause fewer unwanted reactions.

In this study, researchers wanted to know if **GRT6019** was safe and well tolerated when given to healthy participants. To understand this, researchers recorded the number of medical events that occurred at different doses. Medical events may or may not be related to the treatments given in the study. They also measured the amount of **GRT6019** in participants blood at different times during the study to learn about how quickly **GRT6019** moves into, through, and out of the body.

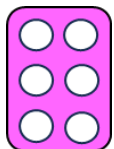
Which medicines were studied?



GRT6019 is a test medicine developed to treat inflammatory conditions. **GRT6019** was taken as capsules or as liquid by mouth.



Placebo (dummy medicine) looks like the test medicine 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.



Prednisolone (a steroid) is an active comparator medicine that is approved for the treatment of inflammatory conditions. **Prednisolone** is taken as tablets. An active comparator medicine usually is an already approved and licensed medicine available in the market for a disease condition.

What was the main objective of the trial?

The main objective of the trial was:

How are different doses of **GRT6019** tolerated in healthy men?

Researchers also wanted to know:

- How much **GRT6019** is taken up by the body and what happens to **GRT6019** blood levels over time?
- How do **GRT6019** blood levels compare when taken as capsules or as liquid?
- How do **GRT6019** blood levels compare when taken with or without food?

When and where did this trial take place?



This trial started on 29 March 2021 and ended on 15 February 2023.



The trial took place at 1 trial centre in Germany.

Which participants were included in this trial?

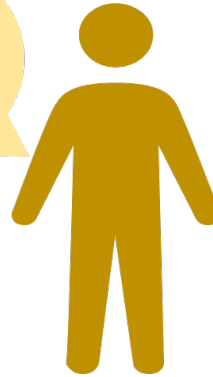
A total of 88 participants took part in this clinical trial.

How old were the participants?

The average age of the participants was 37 years. The youngest participant was 18 years old and the oldest participant was 55 years old.

Were the participants men or women?

All 88 participants were men.



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:

- it was safe for each participant to take part in the clinical trial,
- the results of the clinical trial were valid, and
- the laws and regulations were followed.

People could take part in this trial if they:



were healthy and did not take other medications,



were at least 18 years of age,



had a body mass index (a measure of body weight based on height) between 18.5 and 30 kg/m², and



had a body weight of at least 60 kg.

What happened during this trial?

This was a Phase 1 trial that compared **GRT6019** with **placebo** and with **prednisolone** (a steroid). Phase 1 trials are done to find out how a new trial treatment works in a small number of healthy participants. This helps researchers understand what happens to the test treatment in the body, and if there are any side effects. Side effects are medical events or problems which the study doctor considered related to the study treatment.

Eighty-eight participants were divided into 3 groups.

The groups were:

Group A (72 participants):

Participants in group A received either **GRT6019** or **placebo** as capsules or as a liquid taken by mouth, without food. Researchers randomly assigned participants to receive **GRT6019** or **placebo** using a computer system. This process is called randomization. It means that each participant could be assigned to any treatment, and it helps to make sure that the treatments are distributed fairly. For every 3 participants who received **GRT6019**, 1 participant received **placebo**.

- **GRT6019 as capsules:** Fifty-six out of 72 participants were randomly assigned to receive single doses of either **GRT6019** or **placebo** as capsules. The doses of **GRT6019** were between 0.1 mg and 270 mg. Out of 56 participants, 42 received **GRT6019** and 14 received **placebo** as capsules.
- **GRT6019 as a liquid:** Sixteen out of 72 participants were randomly assigned to receive single doses of either **GRT6019** or **placebo** as a liquid. The doses of **GRT6019** were 50 or 80 mg. Out of 16 participants, 12 received **GRT6019** and 4 received **placebo** as a liquid.

Neither the participants in Group A nor the researchers knew who was given which treatment. This is called a double-blind trial. Trials are sometimes done this way to make sure that trial results are not biased by this information.

Group B (8 participants): participants took a single dose of 20 mg of **prednisolone** as tablets, without food.

Group C (8 participants): participants took a single dose of 15 mg **GRT6019** as a liquid by mouth, with food.

Group B and C received the trial drug in an “open label” manner. This means that participants and the researchers knew who was given which treatment.

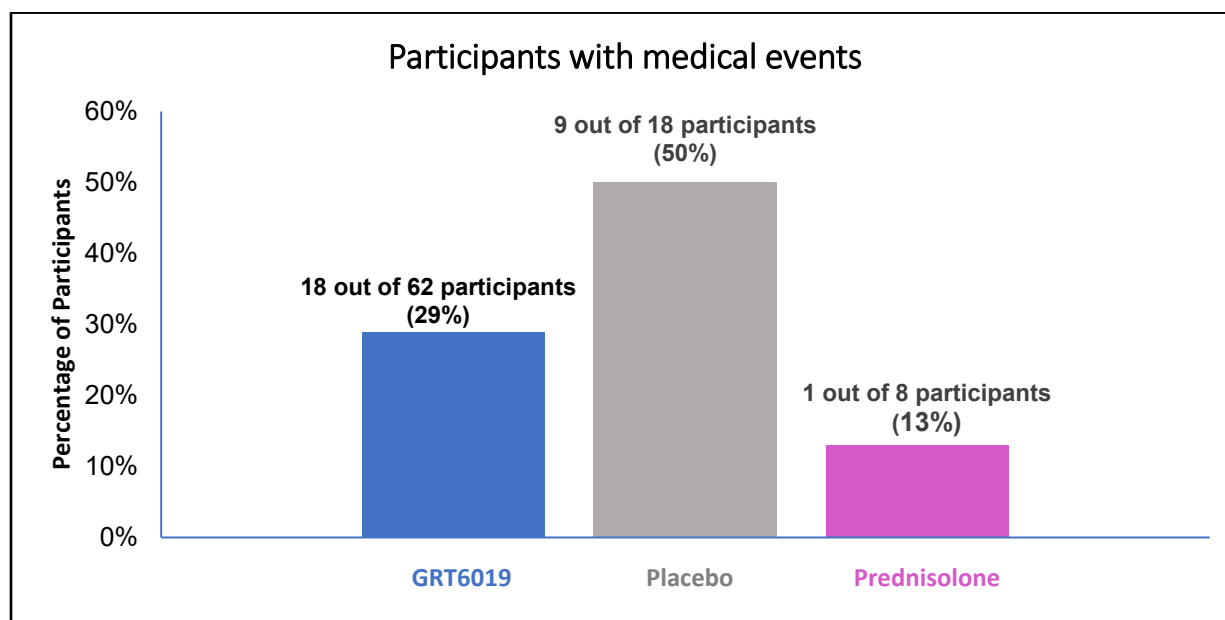
Researchers monitored the health of the participants throughout the trial

An individual participant could be in this trial for about 1.5 months. The trial included a Screening Visit, which occurred 21 to 2 days before the first administration of treatment. Participants were followed up to the Final Examination, which occurred 6 to 23 days after the first administration of treatment depending on which group participants were in.

Of the 88 participants in the study, 62 received **GRT6019**, 18 received **placebo** and 8 received **prednisolone**.

What was the overall result of this trial?

To find out how different doses of **GRT6019** were tolerated, researchers looked at the number of participants with medical events. Researchers keep track of all medical events that participants have when a new treatment is tested. Medical events may or may not be related to the treatments given in the study.



- Eighteen out of 62 (29%) participants on **GRT6019**,
- Nine out of 18 (50%) participants on **placebo**, and
- One out of 8 (13%) participants on **prednisolone** had medical events during the study.

What were the other results of this study?

Researchers measured the amount of **GRT6019** in participants' blood at different times during the study. They found higher amounts of **GRT6019** in participants' blood when **GRT6019** was taken as liquid compared to when it was taken as capsules. **GRT6019** was also taken up faster when taken as a liquid.

Researchers also wanted to know how much **GRT6019** as liquid was available in the blood of participants when taken with or without food. **GRT6019** levels in the blood were lower when taken with food than without food. It also took more time for **GRT6019** to reach its highest blood level when taken with food.

What side effects did participants have in this study?

Side effects are medical problems that happened during the study which the study doctor considered related to the study treatment. Researchers need to compare the results of many studies to know whether a medical problem is indeed finally conclude related to a treatment.

What serious side effects did the participants have?

Serious side effects are those that may cause death, disability, lasting problems, life-threatening conditions, or hospitalization.

No serious side effects or deaths were reported during this study.

How many participants had non-serious side effects?

Non-Serious Side Effects

GRT6019 (Out of 62 participants)	Placebo (Out of 18 participants)	Prednisolone (Out of 8 participants)
2 (3%)	4 (22%)	0

Two out of 62 (3%) participants who took **GRT6019** had non-serious side effects of throat irritation (oropharyngeal discomfort) and tiredness (fatigue).

Four out of 18 (22%) participants who took **placebo** had non-serious side effects of tiredness (fatigue), fungal infection of the skin (fungal skin infections), sore throat (oropharyngeal pain), and a skin condition affecting the corners of the mouth (angular cheilitis).

None of the participants on **prednisolone** had any non-serious side effects.

How many participants stopped treatment because of side effects?

The trial treatment was one dose only per participant. Since all trial participants took the trial treatment, no participants stopped due to side effects.

How was this trial useful for patients and researchers?

The researchers found that **GRT6019** was well tolerated by the trial participants.

Findings from this trial will be used in other trials to learn whether this treatment helps patients with inflammatory conditions.

Other trials for **GRT6019** are ongoing.

The results described in this report are for one trial. The findings of other trials might be different. How **GRT6019** works and how safe it is to use must not be judged on the results of one clinical trial alone.

If you have questions, please contact your trial doctor.

Where can I learn more about this trial?

EudraCT identifier: 2020-003436-24

UTN number: U1111-1255-8596

Sponsor's contact information: 52099 Aachen, Germany

Please consult: [Grünenthal Clinical Trial Portal](#)

Email ID: clinical-trials@grunenthal.com

Date of summary: 06-08-2025