

SDN-CTR-LAYSUM-04

**If you are a volunteer who took part in the clinical trial, thank you for your time and commitment. You made the clinical trial possible.
Thank you for helping us on our way to bringing medicines to patients.**

1 TRIAL NAME

Brief trial name: Safety, tolerability, pharmacokinetics, and pharmacodynamics of oral single doses of GRT6015 in healthy men

Protocol number: HP6015-01

Universal trial number: U1111-1192-1860

2 WHO SPONSORED THIS TRIAL?

Grünenthal GmbH.

3 GENERAL INFORMATION ABOUT THE CLINICAL TRIAL

The test medicine used in this trial was called GRT6015. It was given as a capsule.

The aims of the clinical trial were to find out:

- If increasing doses of GRT6015 were safe and well tolerated.
- How GRT6015 is taken up into the blood and distributed in and eliminated from the body.
- Whether GRT6015 can alter the level of natural substances which are involved in the body's natural immune defense and inflammatory processes.

The clinical trial began on 19 Jul 2017 and ended on 22 May 2018.

The trial was stopped early for business reasons.

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4 WHO WAS INCLUDED IN THIS TRIAL?

36 healthy men were treated at one single site in Germany.

The youngest volunteer was 19 years old and the oldest volunteer was 45 years old. The average (mean) age was 31.4 years.

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

5 WHICH MEDICINES WERE STUDIED?

Each volunteer received GRT6015 (10 mg, 30 mg, or 90 mg) or placebo.

- GRT6015 was the test medicine.
- Placebo is dummy medicine. It looks like a proper medicine but doesn't contain any active ingredients. It was used to find out which effects on the volunteers were due to the procedures and which were due to the test medicine.

For GRT6015 and placebo, neither doctors nor volunteers knew who was given which medicine. This was to make sure that the results of the clinical trial were fair.

6 WHAT WERE THE OVERALL RESULTS OF THE TRIAL?

Single doses of GRT6015 (10 mg, 30 mg, and 90 mg) were safe and well tolerated.

During this clinical trial, some volunteers experienced effects which the trial doctor thought could be side effects of the medicine they had taken. About 1 in 10 volunteers who received GRT6015 had side effects. Volunteers who received placebo did not have any side effects. As the described side effects are only for one clinical trial, the judgement of these results has limitations.

The only side effect for volunteers who received GRT6015 was headache.

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As the dose of GRT6015 increased, the concentration of GRT6015 in the bloodstream also increased.

The highest dose of GRT6015 (90 mg) did appear to alter the level of natural substances which are involved in the body's natural immune defense and inflammatory processes.

The results described in this report are for one clinical trial. The findings of other clinical trials might be different. How well GRT6015 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 family doctor.