



SDN-CTR-LAYSUM-03

**If you are a patient 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: A clinical trial to find out if patients who have pain due to knee osteoarthritis feel less knee pain after using a patch containing lidocaine and diclofenac (GRT7019)

Protocol number: KF7019-01

Universal trial number: U1111-1184-3912

2 WHO SPONSORED THIS TRIAL?

Grünenthal GmbH.

3 GENERAL INFORMATION ABOUT THE CLINICAL TRIAL

Some people feel pain and stiffness in their knees long-term. This illness is called knee osteoarthritis. Patients who have knee osteoarthritis can try to ease their pain by using pain-relieving medicines.

The test medicine used in this trial was GRT7019. It is a patch which patients can stick to a part of their body like the knee. It contains 2 pain-relieving medicines called lidocaine and diclofenac.

The aims of the clinical trial were to find out:

- If patients who have knee osteoarthritis feel less knee pain after using GRT7019 than beforehand.
- If GRT7019 is safe for patients with knee osteoarthritis to use.

The clinical trial began on 12 Jun 2017 and ended on 17 Jan 2018.

SDN-CTR-LAYSUM-03

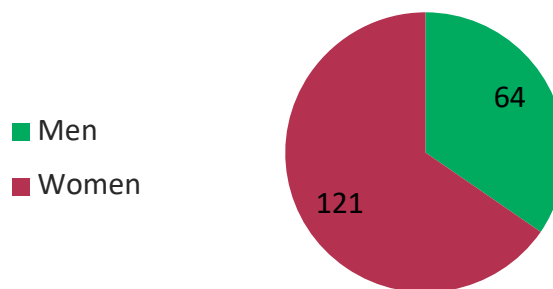
4 WHO WAS INCLUDED IN THIS TRIAL?

185 patients were treated in the clinical trial:

- Austria (14 patients).
- Poland (29 patients).
- Germany (116 patients).
- Spain (26 patients).

The youngest patient was 40 years old and the oldest patient was 79 years old. The average (mean) age was 62 years.

Picture 1: Patients by gender














Patients who took part had been suffering from knee osteoarthritis for at least 3 months. They had mild to moderate knee pain. They had been using pain-relieving medicines at a steady dose for at least 3 months to treat their knee pain.

5 WHICH MEDICINES WERE STUDIED?

Each patient had an equal chance of being put in any one of 4 groups. Patients in the different groups had the medicines shown in Picture 2 every day for 4 weeks.

SDN-CTR-LAYSUM-03

Picture 2: Which patients had which medicines

Name of the group which the patient was in	Daily medicines		
GRT7019	 GRT7019	 Placebo capsules	 Placebo capsules
Placebo	 Placebo patch	 Placebo capsules	 Placebo capsules
Lidocaine	 Lidocaine patch	 Placebo capsules	 Placebo capsules
Diclofenac	 Placebo patch	 Diclofenac capsules	 Pantoprazole capsule

GRT7019 was the test medicine. Lidocaine patches, diclofenac capsules, and pantoprazole capsules were existing medicines. Placebo was dummy medicine.

The 4 groups were used to find out which effects on the patients were due to which medicines.



SDN-CTR-LAYSUM-03

6 WHAT DID THE TRIAL FIND OUT?

The clinical trial found that patients who have knee osteoarthritis felt as much less knee pain after using GRT7019 as after using placebo, lidocaine patches, or diclofenac capsules.

The clinical trial found that GRT7019 was safe for patients with knee osteoarthritis to use.

These are the findings of 1 clinical trial. The findings of other clinical trials might be different.

7 WHERE CAN I FIND MORE INFORMATION ABOUT THIS TRIAL?

You can learn more about this clinical trial by searching for 2016-002611-18 in the [European clinical trials register](#).