

SDN-CTR-LAYSUM-04

If you are a patient who took part in the clinical trial, or if your child took part in this 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 study to look at tapentadol tablets in children and adolescents in pain

Protocol number: KF5503-66

Universal trial number: U1111-1154-4572

2 WHO SPONSORED THIS TRIAL?

Grünenthal GmbH.

3 GENERAL INFORMATION ABOUT THE CLINICAL TRIAL

3.1 When was the trial?

The trial began on 29 Apr 2015 and ended on 15 Oct 2018.

3.2 What was the main objective of the trial?

The medicine that was tested in this trial is called tapentadol PR tablet. When the trial was started, tapentadol PR tablets were already on the market in some countries to treat adults in severe long-term pain. The trial was carried out to test if tapentadol PR tablets can treat children and teenagers in pain.

The aims of the trial were to find out:

- How many children and teenagers in pain clearly get pain relief after they take tapentadol PR tablets or morphine PR tablets for 14 days.

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- How safe it is for children and teenagers in pain to take tapentadol PR tablets for up to 12 months.

4 WHICH PATIENTS WERE INCLUDED IN THIS TRIAL?

4.1 Where did the patients take part in the trial?

The trial took place in these countries:

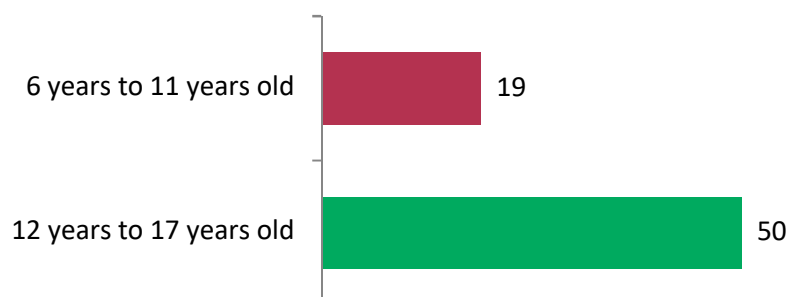
- Belgium (1 patient)
- Bulgaria (18 patients)
- Chile (7 patients)
- France (14 patients)
- Germany (9 patients)
- Hungary (1 patient)
- Italy (4 patients)
- Portugal (9 patients)
- Spain (2 patients)
- United Kingdom (8 patients)

A total of 73 patients joined the trial. 69 of these patients were treated.

4.2 How old were the treated patients?

The youngest patient was 6 years old and the oldest patient was 17 years old. The average age was 13 years. Picture 1 shows the spread of how old the patients were.

Picture 1: Patients by age



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4.3 Were the treated patients boys or girls?

Picture 2 shows how many patients were girls and how many were boys.

Picture 2: Patients by gender



4.4 Which patients were able to take part in the trial?

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

The patients had to be in pain which the trial doctor thought needed treatment with strong painkillers called opioids. The patients had to be older than 6 years and younger than 18 years. They had to weigh at least 17.5 kilograms.

5 WHICH MEDICINES WERE STUDIED?

Patients took tapentadol PR tablets twice a day for 14 days, or morphine PR tablets twice a day for 14 days. Whether a patient took tapentadol PR tablets or morphine PR tablets was decided by chance. It was twice as likely that a patient took tapentadol PR tablets as it was that they took morphine PR tablets.

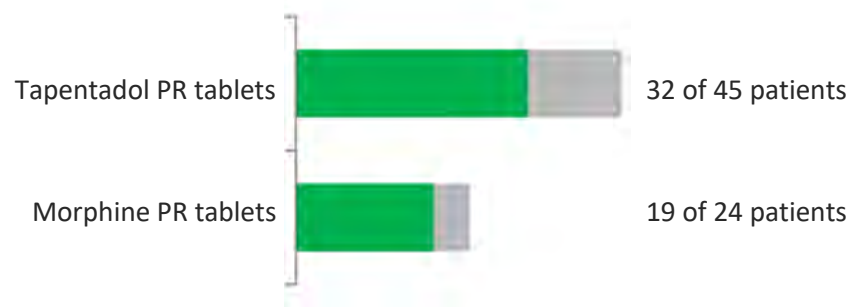
After the first 14 days of treatment, patients who still needed treatment could take tapentadol PR tablets twice a day for up to 12 months.

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6 WHAT WERE THE OVERALL RESULTS OF THE TRIAL?

Picture 3 shows how many patients clearly had pain relief after 14 days of treatment with tapentadol PR tablets or morphine PR tablets.

Picture 3: Clear pain relief after the first 14 days of treatment

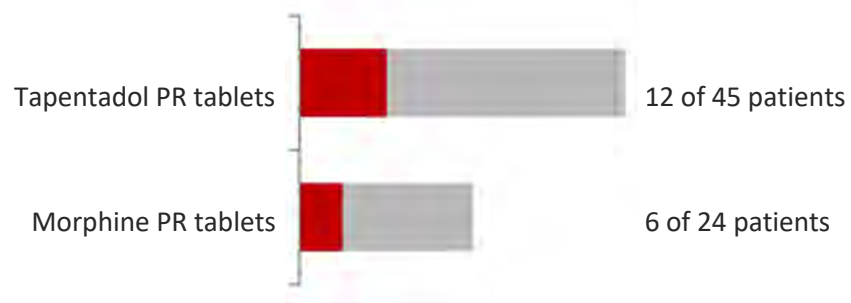


These results showed that the proportion of patients who clearly got pain relief was about the same for patients who took tapentadol PR tablets as for patients who took morphine PR tablets.

During this trial, some patients had effects which the trial doctor thought could be side effects of the medicine they had taken.

Picture 4 shows how many patients had such side effects during the first 14 days of treatment.

Picture 4: Side effects during the first 14 days of treatment



During the first 14 days of treatment, the most common side effects were:

- Feeling sick and headache in patients who took tapentadol PR tablets.

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- Being sick, being constipated, feeling tired, and itch in patients who took morphine PR tablets.

Picture 5 shows how many of the patients who took tapentadol PR tablets for up to the next 12 months had side effects during that time.

Picture 5: Side effects during up to 12 months of treatment



The most common side effects during that time were:

- Feeling sick, being constipated, headache, being sick, feeling tired, and having nightmares.

No patients had long-term side effects up to 12 months after they stopped taking tapentadol PR tablets.

Tapentadol PR tablets were found to be safe in children and teenagers who have pain.

The results described in this report are for one clinical trial. The findings of other clinical trials might be different. How well tapentadol PR tablets work and how safe they are to use must not be judged on the results of one clinical trial alone.

If you have questions, please contact your doctor.