SDN-CTR-LAYSUM-04

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 study to look at tapentadol oral solution in children and adolescents in pain

Protocol number: KF5503/65 R331333PAI3037

2 WHO SPONSORED THIS TRIAL?

Grünenthal GmbH.

3 GENERAL INFORMATION ABOUT THE CLINICAL TRIAL

3.1 When was the trial?

The clinical trial began on 19 Feb 2015 and ended on 14 Mar 2019.

3.2 What was the main objective of the trial?

The medicine that was tested in this trial is called tapentadol. The trial was carried out to test if tapentadol can be useful to treat children and teenagers with moderate/severe short-term pain after surgery, and can reduce the overall use of pain medication called opioids.

The aims of the trial were to find out:

- How well tapentadol decreases pain after surgery in children and adolescents.
- How safe it is for children and adolescents to be given tapentadol.

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:

EU countries

- Bulgaria (15 patients)
- Czech Republic (13 patients)
- Germany (6 patients)
- Spain (13 patients)
- France (8 patients)
- United Kingdom (2 patients)
- Croatia (12 patients)
- Hungary (9 patients)
- Poland (45 patients)

Non-EU countries

- United States (93 patients)

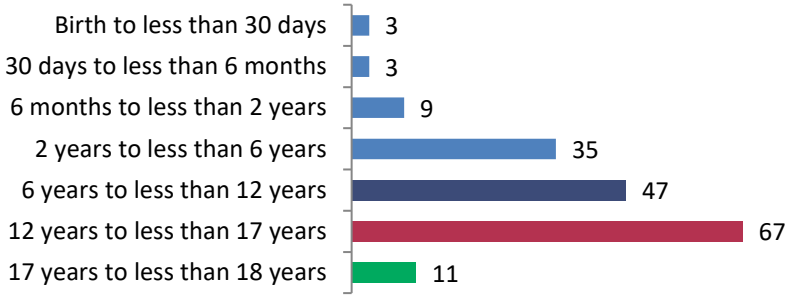
In total, 216 patients joined the trial, and 175 were treated.

4.2 How old were the patients?

The youngest treated patient was less than 30 days old and the oldest patient was 17 years old.

Picture 1 shows the spread of how old the patients were.

Picture 1: Patients by age



4.3 Were the patients girls or boys?

Picture 2 shows how many patients who received trial medicine 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.

Only children from birth to less than 18 years old who were in moderate/severe pain after they had surgery could take part in the trial. They had to weigh at least 2.5 kilograms, but not be obese. They had to have received certain pain medications after the surgery before receiving the trial medicines.

5 WHICH MEDICINES WERE STUDIED?

Each patient had a 2:1 chance of receiving tapentadol or placebo.

- Tapentadol is 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 patients were due to the procedures and which were due to the test medicine.

Each patient was given one of these two trial medicines every 4 hours for 72 hours throughout the trial. Patients were given additional opioid pain medications other than the trial medicine if needed to relief their pain.

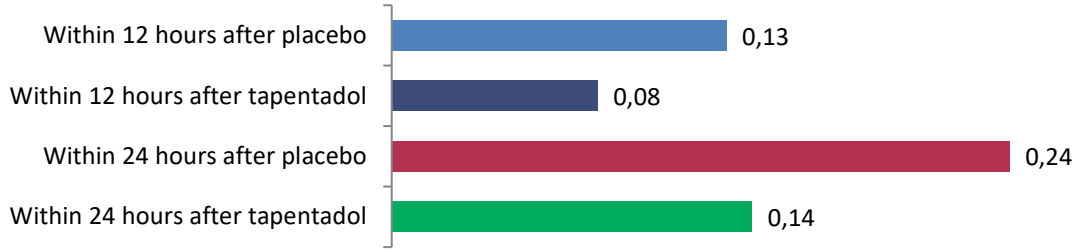
Neither doctors nor patients knew which patients were given which trial medicine (tapentadol or placebo). This was to make sure that the results of the trial were fair.

6 WHAT WERE THE OVERALL RESULTS OF THE TRIAL?

After each patient took trial medicine, the amount of additional opioid pain medication given to the patients was measured within the next 12 hours and 24 hours.

Picture 3 shows that patients from 2 years to less than 18 years old, who had taken tapentadol, needed less additional opioid pain medication in the following 12 hours and 24 hours than patients who had taken placebo. Patients below 2 years of age needed very little additional pain medication at all, as was expected compared to the older children.

Picture 3: Estimated mean amount of additional opioid pain medication (presented as morphine equivalents in mg/kg body weight)



More patients who received tapentadol than patients who received placebo did not need any additional pain medication at all.

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

Picture 4 shows how many patients had any side effects.

Picture 4: Side effects by treatment

The most common side effects in the patients were vomiting, feeling sick to the stomach, being constipated, fever, feeling drowsy, and itch.

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

If you have questions, please contact your family doctor.