

SDN-CTR-LAYSUM-04

**If you are a patient who took part in the clinical trial, or if your child 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: Use of intravenous tapentadol solution for injection for pain after surgery in children from newborn to less than 2 years old, including preterm babies

Protocol number: KF5503-73

Universal trial number: U1111-1157-3228

2 WHO SPONSORED THIS TRIAL?

Grünenthal GmbH.

3 GENERAL INFORMATION ABOUT THE CLINICAL TRIAL

3.1 When was the trial?

The trial began on 23 Apr 2015 and ended on 27 Sep 2018.

3.2 What was the main objective of the trial?

The medicine that was tested in this trial is called tapentadol. When the trial was started, different forms of tapentadol, like tablets and oral solution, were already available in some countries to treat adults with moderate/severe short-term pain. The trial carried out to test if tapentadol can be useful to treat children and teenagers with moderate/severe short-term pain.

SDN-CTR-LAYSUM-04

The aims of the trial were to find out:

- How much tapentadol and how much of its main breakdown product are in the blood of young children who are given tapentadol into a vein to treat moderate/severe short-term pain.
- How safe it is for young children to be given tapentadol into a vein to treat moderate/severe short-term pain.

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:

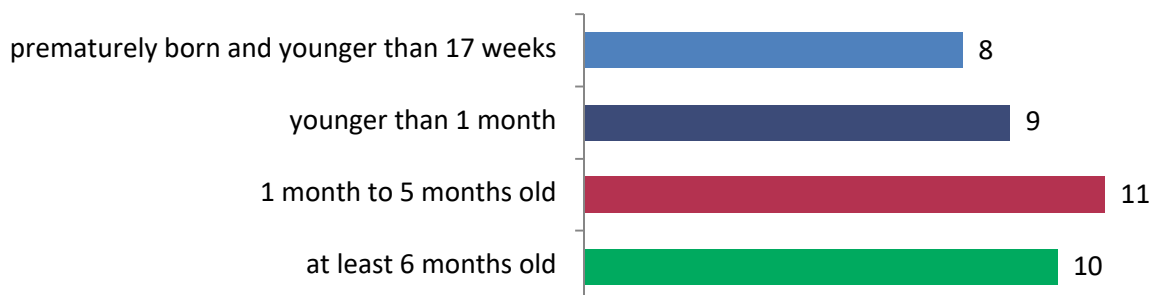
- France (1 patient)
- Hungary (6 patients)
- Poland (36 patients)
- Spain (1 patient)
- United Kingdom (2 patients)

In total, 46 patients joined the trial. 38 of these patients were treated.

4.2 How old were the treated patients?

The youngest patient was 8 days old and the oldest patient was 1 year 8 months old. The average age was 5 months. Picture 1 shows the spread of how old the patients were.

Picture 1: Patients by age

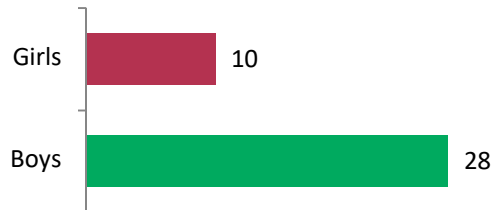


SDN-CTR-LAYSUM-04

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.

Only patients who were in moderate/severe pain after they had surgery or another kind of medical procedure could take part in the trial. They had to be less than 2 years old. They had to weigh at least 1.5 kilograms, but not be obese.

5 WHICH MEDICINES WERE STUDIED?

All patients were given tapentadol into a vein once. This was done slowly over one hour. The amount of tapentadol each patient was given depended on how old and heavy they were.

6 WHAT WERE THE OVERALL RESULTS OF THE TRIAL?

In this trial in young children in moderate/severe short-term pain who were given tapentadol into a vein:

- The level of tapentadol in the blood was about the same as that in adults who have taken tapentadol.

SDN-CTR-LAYSUM-04

- The level of the main breakdown product of tapentadol in the blood was lower than that in adults who have taken tapentadol.
- Tapentadol was found to be safe in these young children.

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