Summary of clinical trial results for the public

Trial Information

Simple trial name: A clinical trial to find out how much tapentadol was in the blood of children who took tapentadol every 4 hours to treat short-term pain

Protocol number: KF5503-75

Trial Sponsor: Grünenthal GmbH

Thank you to the trial patients

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.

You helped us on our way to bringing new medicines to patients.

Important note: You should not use this summary to make decisions about the medical treatments you use. You should always see your doctor for advice about medical treatments.

About this summary

This summary is written to share the results of this clinical trial with the public. It is written in a way that should be easy for most people to understand. It describes why the trial was needed, how it was done, and what the results were.

General information about the clinical trial

Why was this trial needed?

This trial was conducted as a commitment to the European authorities.

Tapentadol Oral Solution is approved to treat adults and children of 2 years and older for moderate to severe pain (e.g., pain caused by an operation or other painful event) which can only be managed with a type of painkiller called opioids. Tapentadol can be given to children only in hospitals.

In this trial, researchers wanted to find out more about what happened to tapentadol once it was inside a child's body, when given as an Oral Solution every 4 hours for up to 3 days. Researchers also studied more about the safety of tapentadol in children.

Which medicine was studied?

Tapentadol

Tapentadol belongs to a group of medicines called "opioids" that stops pain signals from reaching the brain.

What was the main objective of the trial?

The main objective of the trial was to find out:

- how much tapentadol was in the blood of children who took the Oral Solution every 4 hours for up to 3 days?

When was the trial?

Where did this trial take place?

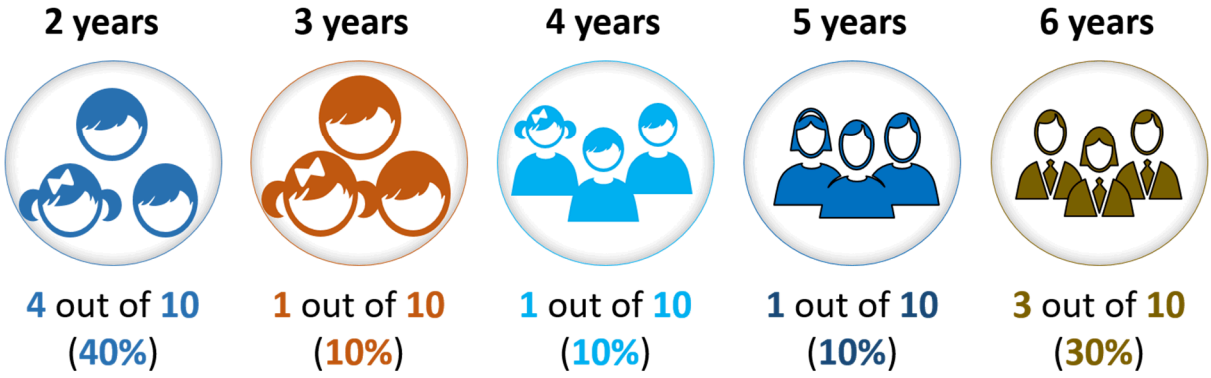
This clinical trial was planned to take place at 3 sites in Poland, but only 2 sites enrolled children.

Which children were included in this trial?

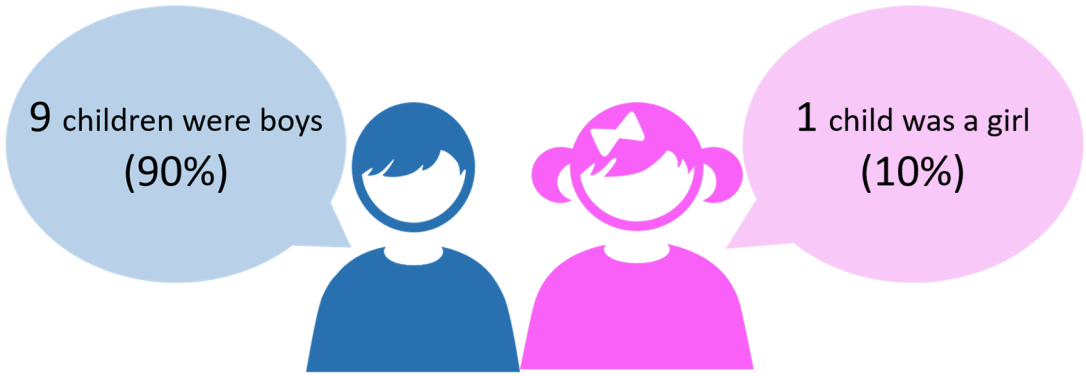
10 children were treated with tapentadol Oral Solution in this clinical trial.

How old were the children?

Children by age



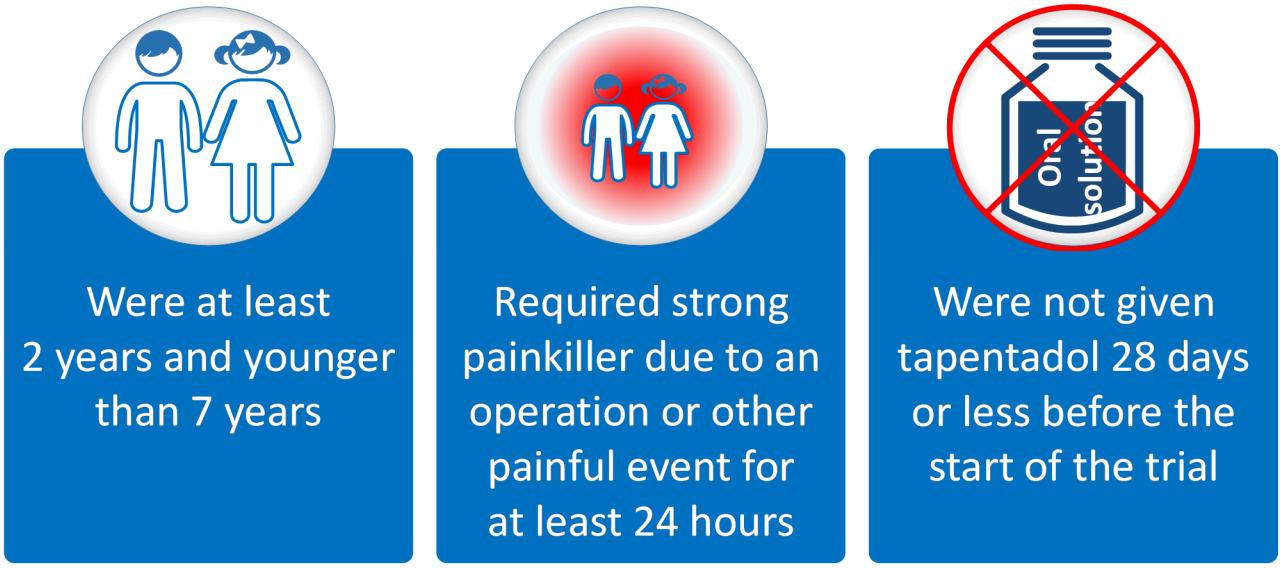
Were the children boys or girls?



Which children were able to take part in the trial?

Children 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 child to take part in the clinical trial. It was also important that the results of the clinical trial were valid, and that the laws and regulations were followed.

Boys and girls could take part in this trial if they:



What happened during this trial?

This was a Phase 2 trial. In Phase 2 trials, the trial medicine is given to a small number of participants with the disease condition to gather information about the effects of the trial medicine in patients to find the best dose.

This study was “open-label”. This means that both the researchers and the parents or legal guardian knew which treatment was given to which participants.

The trial consisted of the following phases:

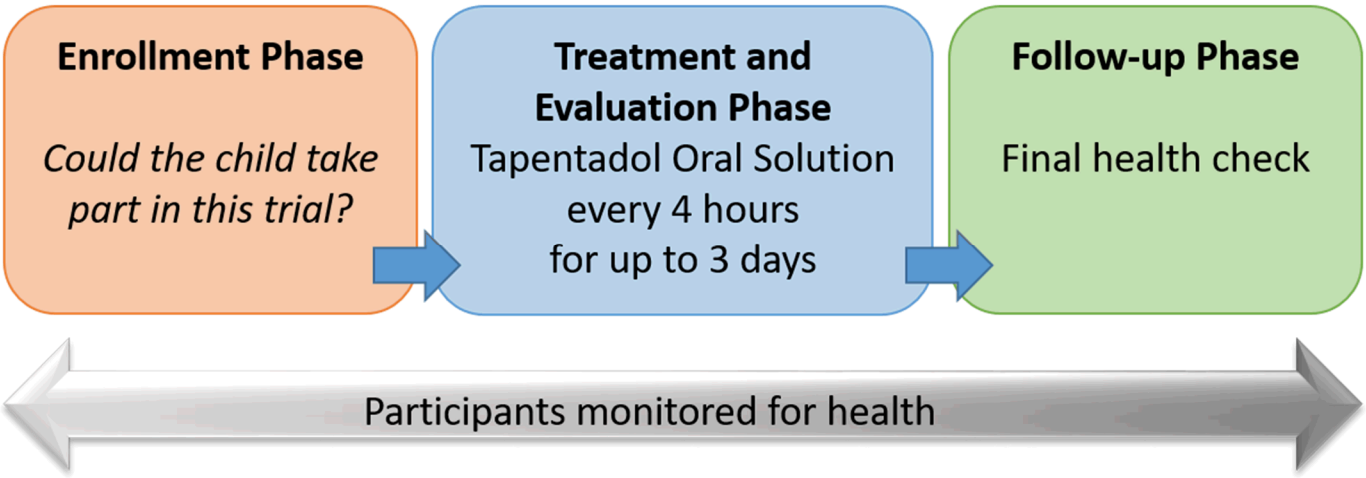
Enrollment Phase: This part of the trial took up to 28 days. Children who were due for an operation, or had an operation or a painful event, and required a strong painkiller for at least 24 hours could join the trial.

Treatment and Evaluation Phase: Children were given a dose of 1.25 milligram (mg) tapentadol per kilogram of their body weight every 4 hours for up to 3 days. All children had some tests and

procedures done during and after stopping the treatment. The treatment, tests, and procedures lasted for up to 4 days. Children remained in the hospital throughout this time. After all tests and procedures were completed, children were allowed to leave the hospital, depending on how well they had recovered. Researchers also collected blood samples from the children at defined time points.

Follow-up Phase: The Follow-up Phase lasted for up to 14 days after the end of the Treatment and Evaluation Phase.

Researchers monitored the health of the children throughout the trial.



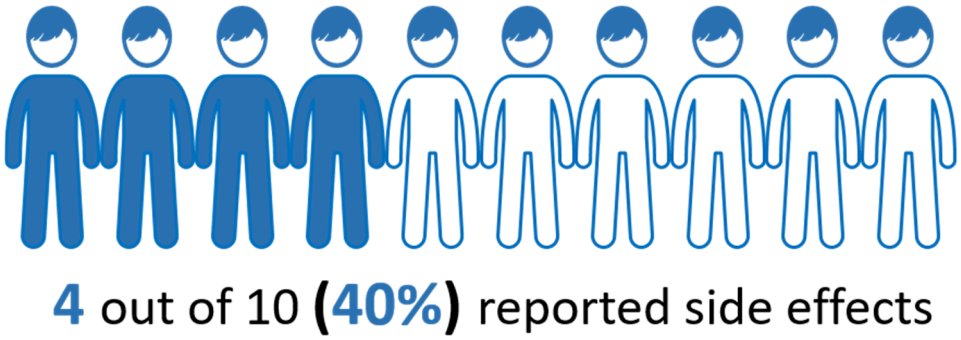
What were the overall results of the trial?

To find out how much tapentadol was in the blood of children who took the Oral Solution every 4 hours for up to 3 days, researchers collected blood samples at defined time points from 1.5 hours after first dose until 10 hours after the last dose.

In this trial, the amount of tapentadol in the blood of children was as expected after the intake of the Oral Solution every 4 hours. The average amount of tapentadol in the blood of children for the 4-hour period between doses was 235 hour*nanogram per milliliter (h•ng/mL).

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

Number of children with side effects



The side effects reported were excessive sweating, constipation, feeling sick to the stomach, and vomiting.

Serious side effects were not reported by any child. Serious side effects are those that may cause death, disability, lasting problems, life-threatening conditions, or hospitalization.

How was this trial useful for patients and researchers?

This trial helped researchers confirm that the amount of tapentadol in the blood of children after several doses of tapentadol Oral Solution every 4 hours was as expected. Researchers also learned about the safety of tapentadol Oral Solution.

Findings from this trial may be used in other trials with tapentadol and may improve treatment for patients with moderate to severe pain.

The results described in this report are for one trial. The findings of other trials might be different. How 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 refer to the patient information leaflet or contact your trial doctor.

Where can I learn more about this trial?

You can find more information about this trial on the following website:

https://www.clinicaltrialsregister.eu/ctr-search/search

Use the EudraCT identifier 2019-000205-77 in the search field.

Full trial name: Open-label investigation of the pharmacokinetic profile, safety, tolerability, and efficacy of multiple administrations of tapentadol oral solution used for treatment of acute pain in children aged 2 years to less than 7 years

Sponsor's contact information: 52099 Aachen, Germany

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