SDN-CTR-LAYSUM-04

If you are a volunteer 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 comparison of how much oxycodone is in the blood of healthy adults after taking different amounts of different tablets on an empty stomach

Protocol number: HP7030-02

Universal trial number: U1111-1203-4898

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 07 Jan 2019 and ended on 26 Feb 2019.

The sponsor stopped the clinical trial early when side effects were noticed in volunteers after a high dose of the compounds was tested.

3.2 What was the main objective of the trial?

The aims of the clinical trial were:

- To show that the amount of a painkiller called oxycodone in the blood increases as increasing numbers of new abuse-deterrent formulation (ADF) tablets are taken.
- To determine how much oxycodone is in the blood after new oxycodone ADF tablets are taken on an empty stomach compared to marketed oxycodone tablets.
- How safe it is for healthy adults to take those tablets.

4 WHICH VOLUNTEERS WERE INCLUDED IN THIS TRIAL?

4.1 Where did the volunteers take part in the trial?

The clinical trial took place in Bulgaria.

40 Volunteers were included in the trial, 32 volunteers were treated, and for 31 volunteers, the amount of oxycodone in the blood was measured.

4.2 How old were the volunteers?

The youngest volunteer was 21 years old and the oldest volunteer was 50 years old. The average age was 35.4 years.

4.3 Were the volunteers men or women?

16 Women and 24 men were treated in the clinical trial.

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

Volunteers 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 volunteer to take part in the clinical trial, that the results of the clinical trial were valid, and that the laws and regulations were followed.

Healthy men and women aged between 18 years and 55 years could take part in the trial.

5 WHICH MEDICINES WERE STUDIED?

Oxycodone ADF tablets and marketed oxycodone tablets were the treatments tested in the trial. Each tablet contained 10 milligrams of oxycodone. Both treatments are “immediate-release” tablets. This means that after a person has swallowed them, they break down quickly in the person’s gut.

Before and after the volunteers were given the ADF tablets or marketed tablets, they were additionally asked to take a so-called “opioid antagonist” medication (naltrexone) to make oxycodone side effects from the ADF and marketed tablets less likely.

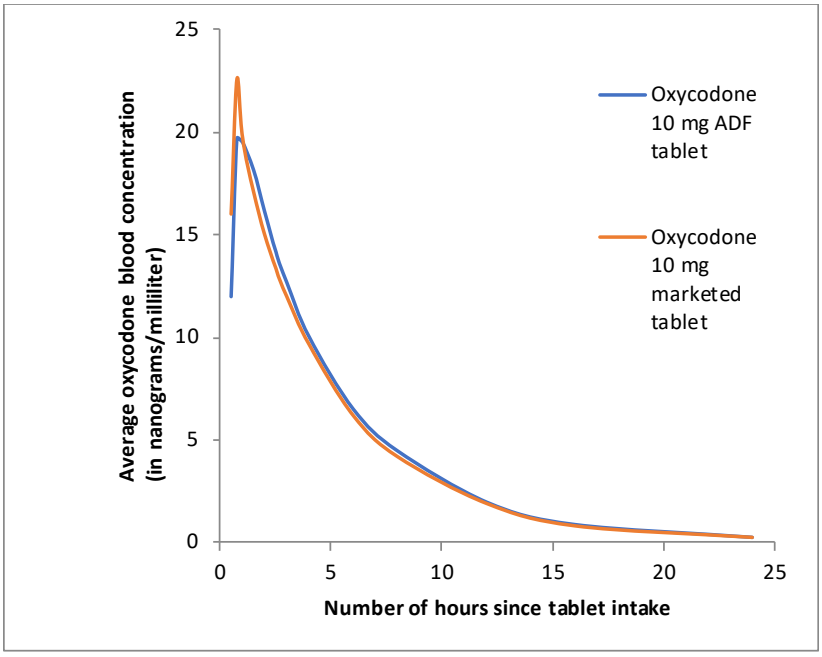
In Part 1 of the trial, 30 volunteers received 1 oxycodone ADF tablet and 31 volunteers received 1 marketed oxycodone tablet. There were at least 5 days between the intake of the first and the second tablet. The order in which each volunteer took the tablets (first ADF or first marketed tablet) was decided by chance.

In Part 2 of the trial, 1 volunteer received 5 oxycodone ADF tablets and 1 volunteer received 5 marketed oxycodone tablets.

6 WHAT WERE THE OVERALL RESULTS OF THE TRIAL?

Picture 1 shows how much oxycodone on average was in the blood of the volunteers after they took 1 ADF tablet or 1 marketed tablet in Part 1 of the trial.

Picture 1: Results for 1 oxycodone ADF tablet and 1 marketed tablet



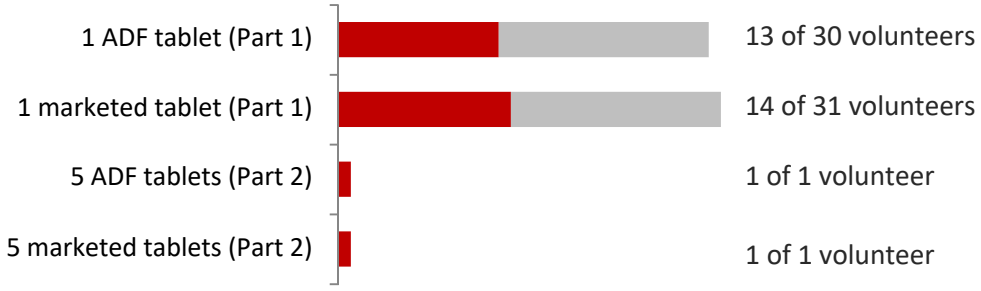
These results showed that:

- About as much oxycodone was in the blood of the volunteers after they took 1 ADF tablet as after they took 1 marketed tablet, on an empty stomach.

During this clinical trial, some volunteers experienced effects which were related to the treatment they received and which were mainly typical oxycodone side effects.

Picture 2 shows how many volunteers had such side effects.

Picture 2: Number of volunteers with oxycodone side effects



The most common side effect was slow heart beat in 7 of 30 volunteers who took 1 oxycodone ADF tablet and in 11 of 31 volunteers who took 1 marketed tablet. Volunteers who took 5 ADF or marketed tablets also had slow heart beat or a low oxygen saturation in their blood. Because of these side effects, the sponsor stopped the trial early.

The results described in this report are for 1 clinical trial. The findings of other clinical trials might be different. How well oxycodone ADF tablets and marketed tablets work, and how safe they are to use must not be judged on the results of 1 clinical trial alone.

If you have any questions, please contact your doctor.