

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 tablets on a full stomach and on an empty stomach

Protocol number: HP7030-01

Universal trial number: U1111-1203-4804

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 03 Sep 2018 and ended on 24 Oct 2018.

3.2 What was the main objective of the trial?

The aims of the clinical trial were to find out:

- How much oxycodone is in the blood of healthy adults after they take one abuse deterrent formulation (ADF) tablet on a full stomach, compared to on an empty stomach.
- How much oxycodone is in the blood of healthy adults after they take one marketed tablet on a full stomach, compared to on an empty stomach.
- How safe it is for healthy adults to take those tablets.

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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.

43 joined the trial. 32 of these volunteers were treated.

4.2 How old were the treated volunteers?

The youngest volunteer was 20 years old and the oldest volunteer was 52 years old. The average age was 36.9 years.

4.3 Were the treated volunteers men or women?

Half of the volunteers were men, and half of the volunteers were women.

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.

Only healthy men and women could take part in the trial. They had to be aged between 18 years and 55 years.

5 WHICH MEDICINES WERE STUDIED?

ADF tablets and marketed tablets. Both of these contain a drug called oxycodone. Both of these are called 'immediate release' tablets. This means that after a person has swallowed one of these tablets, the tablet breaks down quickly in the person's gut.

During the trial, the trial doctor asked each volunteer to take 4 tablets:

- One ADF tablet, on an empty stomach.
- One ADF tablet, on a full stomach.

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- One marketed tablet, on an empty stomach.
- One marketed tablet, on a full stomach.

The order in which each volunteer took the 4 tablets was decided by chance.

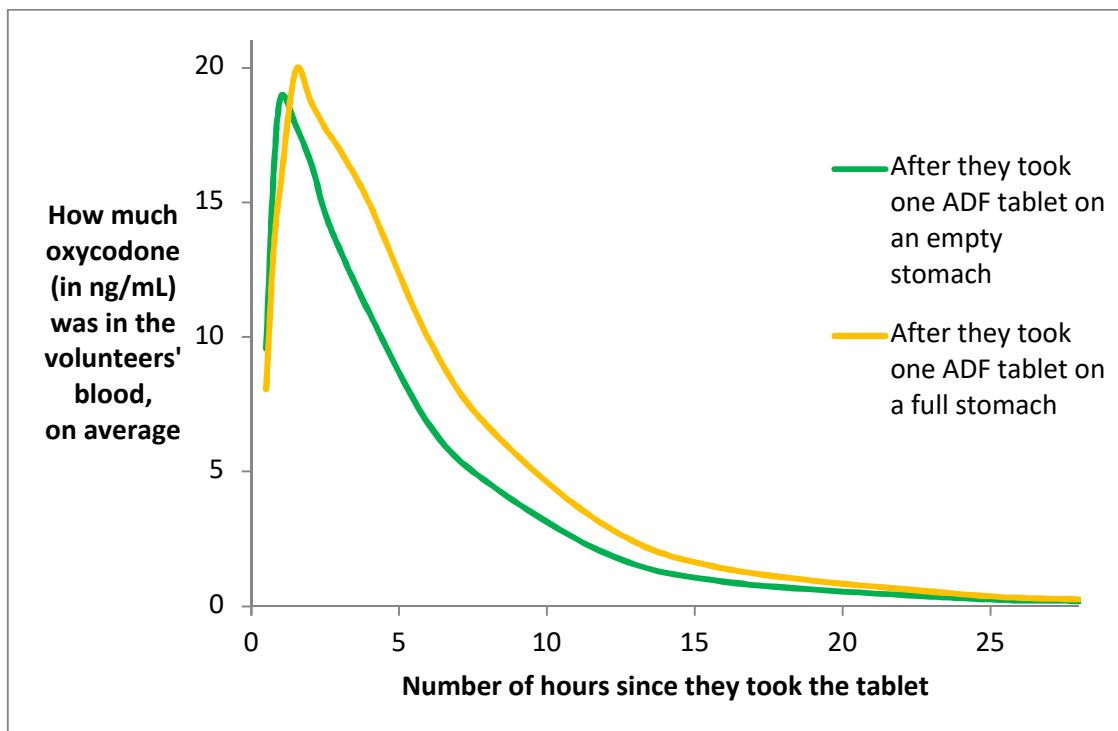
After a volunteer took one tablet, there were at least 5 days before they took the next tablet.

Some volunteers did not take all 4 tablets, because they left the trial early.

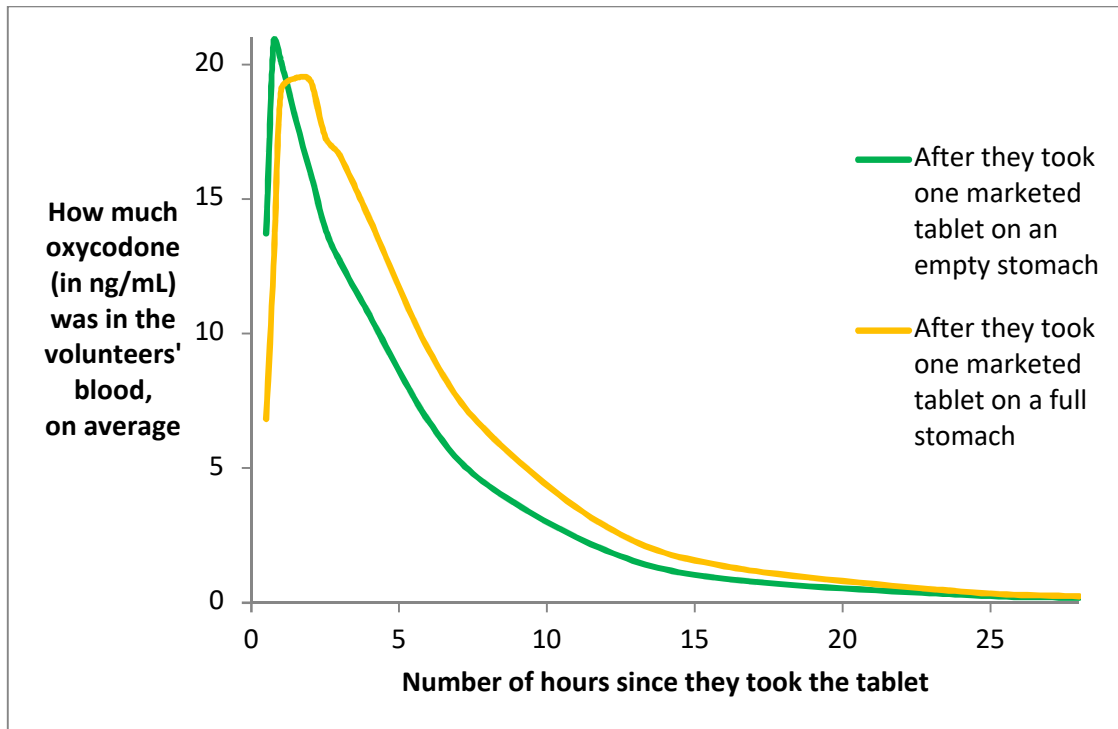
6 WHAT WERE THE OVERALL RESULTS OF THE TRIAL?

Picture 1 and Picture 2 show how much oxycodone on average was in the blood of the volunteers after they took the ADF tablets and the marketed tablets.

Picture 1: Results for the ADF tablets



Picture 2: Results for the marketed tablets



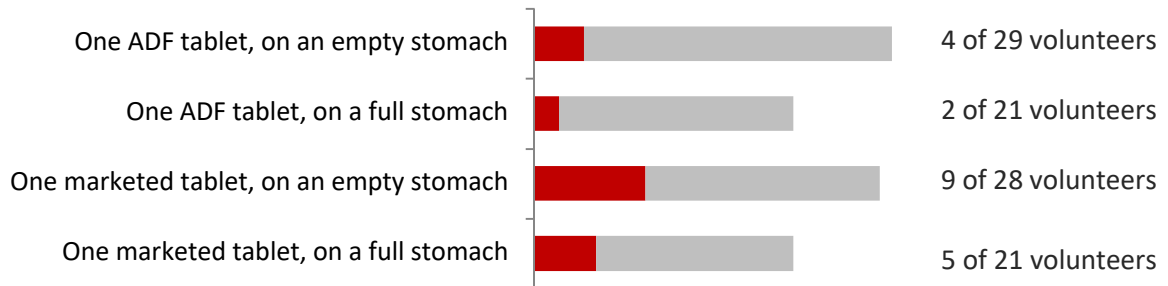
These results showed that:

- Slightly more oxycodone was in the blood of the volunteers after they took one ADF tablet on a full stomach than on an empty stomach.
- Slightly more oxycodone was in the blood of the volunteers after they took one marketed tablet on a full stomach than on an empty stomach.
- About as much oxycodone was in the blood of the volunteers after they took one ADF tablet as after they took one marketed tablet, on an empty stomach.
- About as much oxycodone was in the blood of the volunteers after they took one ADF tablet as after they took one marketed tablet, on a full stomach.

During this clinical trial, some volunteers experienced effects which the trial doctor thought could be side effects of the medicine they had taken. Picture 3 shows how many volunteers had such side effects. The most common of these side effects were being sick and feeling sick.

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Picture 3: Side effects which may have been caused by the tablet taken



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

If you have any questions, please contact your doctor.