

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 likely it is that different tablets of oxycodone will be broken up and snorted by adults who sometimes take drugs for pleasure

Protocol number: HP7030-03

Universal trial number: U1111-1203-4920

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 24 Jul 2018 and ended on 20 Nov 2018.

3.2 What was the main objective of the trial?

The aims of the clinical trial were to find out:

- How likely it is that adults who sometimes take drugs for pleasure snort crushed “abuse deterrent formulation” (ADF) oxycodone tablets, compared to oxycodone powder.
- How safe it is for these adults to snort crushed ADF oxycodone tablets and oxycodone powder.

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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 Canada.

123 volunteers joined the trial. 38 of these volunteers were treated in the main part of the trial.

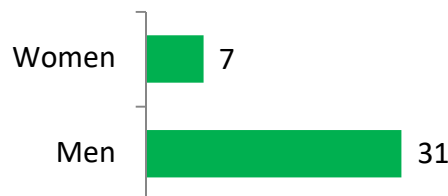
4.2 How old were the treated volunteers?

The youngest volunteer was 22 years old and the oldest volunteer was 53 years old. The average age was 35.7 years.

4.3 Were the treated volunteers men or women?

Picture 1 shows how many volunteers were women and how many were men.

Picture 2: Volunteers by gender



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. They had to have snorted drugs for pleasure in the past.

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5 WHICH MEDICINES WERE STUDIED?

ADF oxycodone tablets, oxycodone powder, ADF dummy tablets, and dummy powder.

ADF dummy tablets look exactly like ADF oxycodone tablets, but contain no oxycodone. Dummy powder looks exactly like oxycodone powder, but contains no oxycodone. These dummy medicines were used to find out which effects on the volunteers were due to the procedures and which were due to ADF oxycodone tablets or oxycodone powder.

During the trial, the trial doctor asked each volunteer to snort 3 combinations of the medicines:

- Dummy powder, then crushed ADF oxycodone tablets.
- Oxycodone powder, then crushed ADF dummy tablets.
- Dummy powder, then crushed ADF dummy tablets.

After a volunteer snorted one combination, there were 3 days before they snorted the next combination. The order in which each volunteer snorted the 3 different combinations was decided by chance. Neither doctors nor volunteers knew what the order was. This was to make sure that the results of the clinical trial were fair.

One volunteer did not snort all 3 combinations because this volunteer left the trial early.

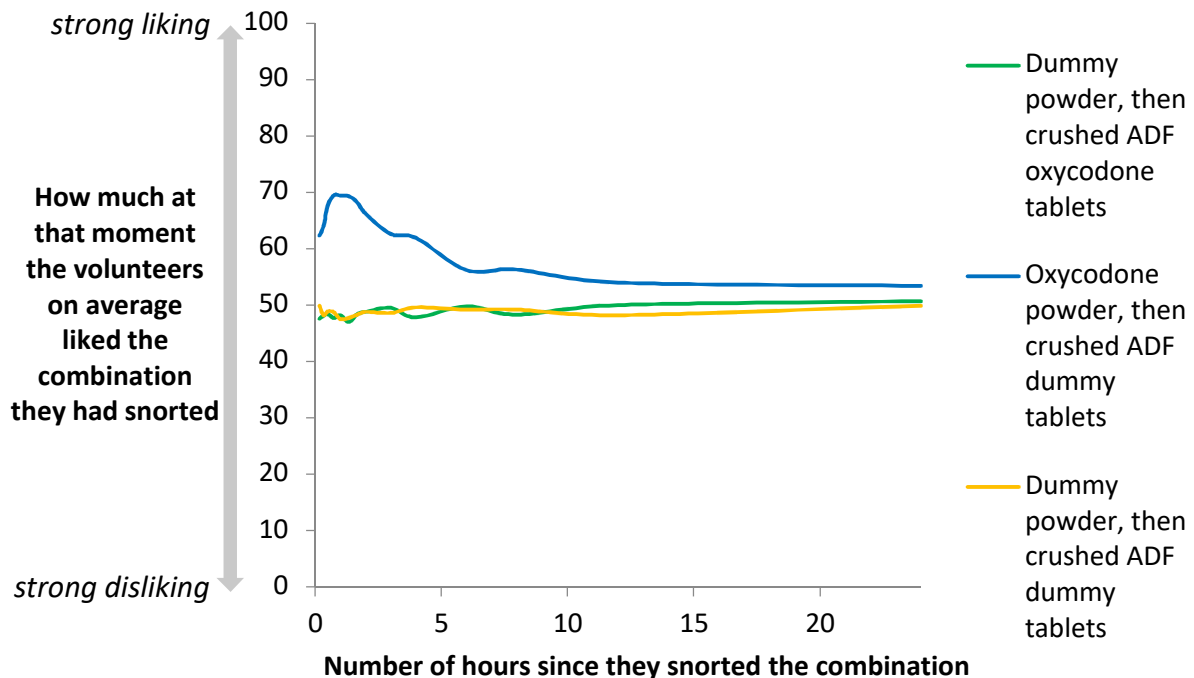
6 WHAT WERE THE OVERALL RESULTS OF THE TRIAL?

After a volunteer had snorted a combination of the medicines, the trial doctor asked them at different times to choose any number between 0 and 100 to show how much they liked the combination at that moment in time. Choosing 0 showed they strongly disliked it. Choosing 50 showed they neither liked nor disliked it. Choosing 100 showed they strongly liked it.

Picture 1 shows how much on average the volunteers liked the combinations of medicines at different moments in time after they had snorted them.

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Picture 1: Average drug liking at different moments in time

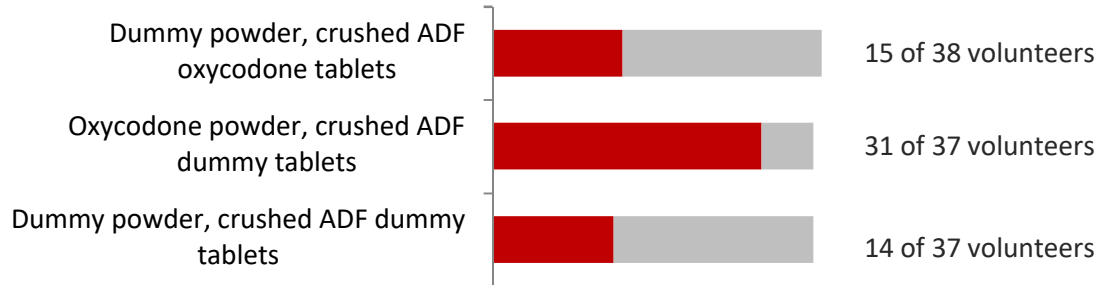


The results showed that, on average, the volunteers liked the combination of dummy powder and crushed ADF oxycodone tablets less than the combination of oxycodone powder and crushed ADF dummy tablets. On average, the highest number for drug liking that the volunteers chose for the combination of “dummy powder and crushed ADF oxycodone tablets” was clearly lower than the highest number that the volunteers chose for the combination of “oxycodone powder and crushed ADF dummy tablets”. These results suggest that adults who sometimes take drugs for pleasure might be less likely to snort crushed ADF oxycodone tablets than oxycodone powder.

During this clinical trial, some volunteers experienced effects which the trial doctor thought could be side effects of the combinations of medicines they had snorted. Picture 2 shows how many volunteers had such side effects. The most common of these side effects were blocked nose (in all treatment groups), feeling intensely excited and happy (in the group which took oxycodone powder and crushed ADF dummy tablets), and itching (in the group which took oxycodone powder and crushed ADF dummy tablets).

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Picture 2: Side effects which may have been caused by the medicines snorted



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

If you have questions, please contact your doctor.