

Lay summary

Study to test how patients with cystic fibrosis like a new form of CREON for digestive problems.

1. Clinical Trial Identification
Researchers look at the results of many studies to decide which medicines work best and are safest for the patients. This summary reports the results of only one study. Other studies may give different results. A new form of CREON was used for the first time in this study. Hence, this study was considered a Phase I clinical trial. All participants received the same treatment. Both doctors and participants knew the treatment given and received.
1.1 Title of the Study
Short Title: Study to test how patients with cystic fibrosis like a new form of CREON for digestive problems. Study Official Title: Open-label single-arm, multicentre clinical trial to evaluate patient acceptability of a new CREON formulation of Pancreas Powder gastro-resistant pellets in patients with cystic fibrosis suffering from pancreatic exocrine insufficiency.
1.2 Protocol Number
PANC-GRP-3001
1.3 EU Study Number
2023-503256-27-00
1.4 Other Identifiers
Not applicable.
1.5 Study Abstract
Why was this study done?
By doing this study, the researchers wanted to find out how people with cystic fibrosis like a new form of CREON, a medicine used to digest food.
What is cystic fibrosis?
Cystic fibrosis is a disease that affects the lungs and stomach. It also affects the pancreas, which helps break down food. In people with cystic fibrosis, the pancreas does not make enough enzymes. These enzymes help the body to absorb the food we eat. Without these enzymes, one may suffer from stomach pain, constipation, or loose motion. Therefore, people with cystic fibrosis often have trouble in digesting their food.
Which medicine is prescribed for pancreatic exocrine insufficiency in patients having cystic fibrosis?
Doctors often give medicines containing enzymes from pancreas of animal origin. With these medicines the patients are supplemented with enzymes. One medicine, called CREON, is used for such therapy. It helps people with cystic fibrosis digesting their food. It replaces the enzymes that the pancreas cannot make.
Why is different type of CREON formulation required for pancreatic exocrine insufficiency in patients having cystic fibrosis?
CREON usually comes in the form of capsules. People need to swallow them after every meal and snack. Some people need to take many capsules each day, which can be hard and uncomfortable. Especially, for people who find it hard to swallow the capsules. To make it easier,

a new form of CREON was made. This new form has the same enzymes as the capsules. It can be mixed with water and swallowed.

To see the study results and check if the new CREON formulation is safe, go to **section 8**.

1.6 Study setup

This was the first time the new CREON form was tested in people. Every patient who took part in the study got the same medicine. Both the doctors and the patients who took part in the study knew about the medicine that was being tested.

2. Who sponsored the study?

Sponsor:

Meda Pharma GmbH & Co. KG (A Viatris Company)

Contact:

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Email address: EUClinicalTrials@viatris.com

Phone: +49 (0) 6172 888 -01

3. General information about the study

3.1 Where was the study done?

This study took place in the following two countries:

- Germany
- United Kingdom

3.2 When did the study start and end?

The study began in May 2024, and ended in December 2024.

3.3 What was the main goal of the study?

The goal was to see how people with cystic fibrosis felt about using the new CREON form. The study did not check if the new form made people healthier. The study only looked at how easy and safe the new form was to use.

4. Who took part in the study?

4.1 How many patients took part in the study?

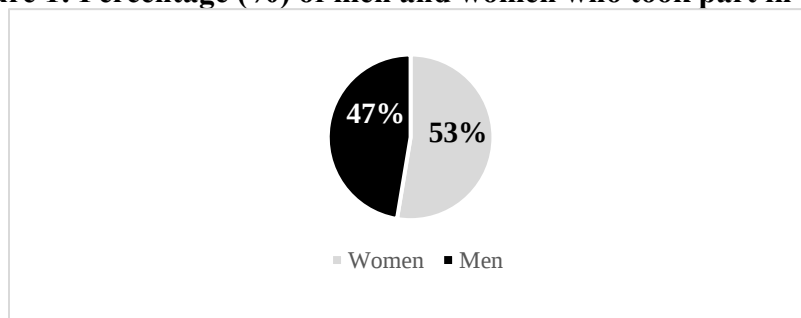
A total of 58 patients joined the study:

- 50 were from Germany
- 8 were from the United Kingdom

4.2 What was their age and gender?

- The patients in the study were between 19 and 62 years old. On average, the patients were 35 years old.
- The number of men and women who joined the study is shown in [Figure 1](#).

Figure 1: Percentage (%) of men and women who took part in the study



Grey shows the number of women who took part in the study which was 30.
Black shows the number of men who took part in the study which was 27.

- Out of the 58 people:
 - 30 were women
 - 28 were men

4.3 Inclusion and exclusion criteria

Who could join the study?

Both men and women could join the study if they:

- Were 18 years or older
- Had cystic fibrosis (confirmed by medical tests)
- Had been taking CREON capsules for at least 4 weeks
- Took at least 2 CREON capsules with each main meal
- Were willing to follow the study rules
- Signed a form saying they agreed to join the study

Who could not join the study?

Patients could not join the study if they:

- Had serious health problems
- Were allergic to CREON or its ingredients
- Had rare digestion problems that made it unsafe to take the new form of CREON
- Were pregnant or breastfeeding
- Had a recent illness or infection
- Had drug or alcohol problems since last 2 years
- Were part of another medical study in the last 3 months
- Did not want to follow the study rules
- Could not attend study visits
- Were in detention or were not given permission to join

5. Medicine tested in the study

Which medicine was tested in this study?

The study tested a new form of CREON, a medicine that helps people with cystic fibrosis in digesting food. Instead of swallowing capsules, the new form can be mixed with water and swallowed.

Everyone in the study took the same CREON form. No other medicine was used or compared in this study.

How was the new form of CREON given to the patients?

For the first week, patients took their usual CREON capsules. In the second week, they switched to the new CREON form. After one more week, the patients had a follow-up call.

Directions for use:

- Take the medicine orally.
- Swallow the medicine and do not chew or keep it in your mouth.

6. Medical problems/side effects that were reported during the study

Side effects are unwanted health problems (such as headache) that happened during the study and were thought to be related to the new CREON form. Not everyone in the study had side effects.

Serious side effects

- None of the patients died during the study.
- None of the patients had any life-threatening reactions or needed to go to the hospital.
- None of the patients had any serious side effects.
- Only two patients (3.5%) had severe non-serious side effects: one had stomach pain, and one had gas.

Common side effects

Some of the common related side effects experienced by the patients while they took CREON capsules and while they switched to the new CREON form during the study can be found in the below [Table 1](#).

Table 1: Related side effects experienced by patients

Side Effect	Number of Individuals	Percentage
Gas	17	30%
Stomach pain	11	19%
Upper stomach pain	4	7%
Diarrhea (loose motion)	4	7%
Soft poop	4	7%
Nausea	2	4%
Constipation	2	4%
Mouth sores	1	2%
Pain in the mouth	1	2%

These side effects were mostly mild or moderate and did not require further medical support.

Other observations

A few people had minor mouth problems like irritation or painful sores. This may have happened because they chewed the medication instead of swallowing it properly. None of the patients had serious allergic reaction or major health problems from the medication.

7. Overall results of the clinical study

Out of the 58 patients who joined the study, 55 finished it. Three patients left the study in between. Either because they had side effects or found it hard to follow the study rules.

Goal: To find out how cystic fibrosis patients like using a new form of CREON; a medicine that aids in digesting food.

Method: Patients answered a questionnaire with 12 questions about how easy and pleasant it was to use the new form. Each question was rated from 0 (worst) to 10 (best).

Key results

What did the patients think about using the new CREON form?

Most patients found the new CREON form easy to use. They said opening the package of the medicine was very easy and gave it a score of 9 out of 10.

Patients did not think the units of the medicine they had to take was a problem. They gave this a score of 8 out of 10.

The time it took to take the dose and how convenient it was got a lower score. Patients gave a score of 5 out of 10 for both these.

Was it easy to swallow the new form contents?

Patients had different opinions about how easy it was to swallow the new form. On average, they gave it a score of 7 out of 10.

Did the patients feel full after taking the new form?

Most patients did not feel full after taking the medicine. They gave this a score of 9 out of 10.

Did the patients like the taste and texture of the new form?

Some patients did not like the taste and mouth feeling of the medicine. They gave the taste a score of 7 out of 10 and the texture a score of 6 out of 10.

Most patients did not notice a strong aftertaste. They were okay with it and gave it a score of 8 out of 10.

8. General summary of the study results

This study looked at how safe and easy it was to use a new form of CREON instead of capsules. Most of the patients found the new form easy to use. However, some patients did not like preparing the dose or the taste of the new form. About one-third of the patients said they might use both capsules and the new form. The new form was safe and did not cause any serious side effects.

Limitations of the study

It was not easy to find patients to take part in the study. Only 58 patients joined, but the plan was to include more. Because of this, the results may not apply to everyone.

Most of the people were from Germany, and only a few were from the UK. So, the results might not be the same for people in other countries.

The study lasted only three weeks, and patients used the new form for just one week. This means it is unknown what happens if people use the new form for a longer time.

Also, everyone in the study had already used CREON capsules before and did not have trouble swallowing. So, the results might be different for people who are new to the medicine or who have trouble swallowing pills.

How the study helps future research

The results from this study can help with future research. They can be used to see how good the new form of CREON helps people with cystic fibrosis and problems with the pancreas. The results can also help compare the new form with other medicines, see how the new form works with other medicines, and support approval for using the new form as a treatment.

The study shows that the new form might be a good choice for people who have trouble swallowing capsules, need a higher dose of medicine, or want more flexibility in how they take their medicine.

9. Are more studies planned?

Right now, there is no information about any new studies.

However, more research in the future could help make the medication better. It could also help test the new form in different groups of people, especially those who have trouble swallowing the capsules or need higher doses of medicine.

10. Where can you find more information about this study?

If you have questions about the study results, you can talk to your doctor or the staff at the clinic, hospital, or study site you visit.

For more details, you can visit the [Search for clinical trials - EMA](#).