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Evaluation of acceptability of a new CREON formulation containing Pancreas Powder gastro-resistant pellets for oral use in patients with cystic fibrosis (CF) suffering from pancreatic exocrine insufficiency type of CF condition, which is characterized by maldigestion due to insufficient endogenous enzyme production and /or secretion

Submission date
12/12/2023

Recruitment status
No longer recruiting

Registration date
25/04/2025

Overall study status
Completed

Last Edited
20/05/2025

Condition category
Digestive System

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
With this study, the Sponsor would like to find out if patients with cystic fibrosis (CF) tolerate the new CREON formulation containing Pancreas Powder gastro-resistant pellets for oral use. Until now, they have used digestive enzymes in hard capsule form with or after meals and snacks in individual doses. Higher dosages may require them to take several and/or larger hard capsules, which may be inconvenient or unpleasant. CREON new formulation has been developed to use the same gastro-resistant pellets as CREON capsules. The study medication for comparison (CREON capsules) used in this clinical trial is a medication of animal origin (porcine). CREON capsules have already been approved in many countries where the study is being conducted (Germany, United Kingdom and the Netherlands) for the treatment of pancreatic malfunction associated with digestive problems (pain in the stomach, bloating (gas), and abnormal stool consistency/frequency). They are known by their trade names CREON 10000 or CREON 25000. The CREON capsules will be used by the participant in the 'Run-in-period' part of the study treatment. However, the new CREON formulation has not yet been approved and has not been tested in humans until now. CREON new formulation (investigational drug) uses the same digestive enzymes in the same gastro-resistant pellets as CREON capsules but with additional ingredients. The CREON capsules and CREON new formulation, both contain pancreatic enzymes from pigs with fat, sugar and protein-splitting properties as the active ingredient. The active ingredient is called porcine pancreas powder with amylase/lipase /protease activity. These enzymes are treated in such a way (being coated) so they don't release

before they reach the stomach. The main aim of this clinical trial is to assess if patients like the new CREON formulation. The study wants to find out if the participants are interested in switching to the new formulation from the current capsules. The study will also assess clinical symptoms, safety and tolerability of ingested doses of the new formulation.

Who can participate?
Adult patients aged 18 years old and over with cystic fibrosis and on treatment with PERT (CREON capsules)

What does the study involve?
A total number of 120 patients will participate in this study if they meet the eligibility criteria and upon signing an Informed Consent Form.
The study will begin with a one-week Run-in period. During this time study participants will continue using their standard PERT treatment with CREON capsules provided by the sponsor. After that week, study participants will be enrolled into the study (Visit 2) and administer CREON new formulation in a dose-comparable manner for one week (until Visit 3).
Treatment will be administered per oral (PO) per meal/snack for 7 days. All selected study participants have been diagnosed with CF and are already on regular PERT treatment with CREON capsules.
A final follow-up telephone call will be scheduled one week after Visit 3.
Participants will be instructed to record the date, time, dose of CREON administered, number of capsules/new formulation, circumstance of use, location of use as well as clinical symptoms, adverse event occurrence, use of medication for acute conditions, as well as local tolerability in a paper-based diary. At the end of the treatment, patients will be answering a questionnaire which will help to know about the acceptability of the new formulation.

What are the possible benefits and risks of participating?
Benefits: Intake of CREON capsules and CREON new formulation may ease your digestive problems or even lead to freedom from symptoms. However, the effect cannot be guaranteed in individual cases. CREON new formulation might be able to improve swallowing problems.

Risks: As with any medication, previously unknown side effects may occur with the use of CREON capsules (standard of care drug/comparator) and CREON new formulation (study drug under investigation).

The expected adverse events for CREON new formulation are similar to the CREON capsules.

However, incorrect intake of the CREON new formulation content can also lead to: oral/mouth pain, Irritation (so-called stomatitis), inflammation of the oral cavity (inside of mouth), bleeding inside of mouth, ulcer formation in the mouth, i.e. small, painful wounds in the mouth

Where is the study run from?
Meda Pharma GmbH & Co.KG (A Viatris Company)

When is the study starting and how long is it expected to run for?
September 2023 to March 2025

Who is funding the study?
Meda Pharma GmbH & Co.KG (A Viatris Company)

Who is the main contact?
EUClinicalTrials@viatris.com

Contact information

Type(s)
Scientific

Contact name
Dr Kristina Marschall

Contact details
Global Clinical Science Department
-
Germany
-
None provided
EUClinicalTrials@viatris.com

Type(s)
Principal Investigator

Contact name
Dr Daniel Peckham

Contact details
Beckett Street
Leeds, West Yorkshire
United Kingdom
LS9 7TF
+44 (0)11 32067170
D.G.Peckham@leeds.ac.uk

Additional identifiers

EudraCT/CTIS number
2023-503256-27

IRAS number
1008425

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
PANC-GRP-3001, CPMS 60190

Study information

Scientific Title

Open-label single-arm, multicenter 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.

Study objectives
• Evaluation of lipase dose used (per main meal, snack and over the day, number of capsules / new formulation)
• Evaluation of switch potential from CREON capsules to new formulation or to a combination of capsule and new formulation including situations eligible for switch
• Evaluation of clinical symptoms (stool frequency, stool consistency, abdominal pain, flatulence)
• Evaluation of safety and tolerability (including local tolerability)

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 23/07/2024, London-Chelsea Research Ethics Committee (2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; +44 (0)2071048141; chelsea.rec@hra.nhs.uk), ref: 24/LO /0031

Study design
Open-label active-comparator-controlled study

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Home, Hospital, Telephone

Study type(s)
Other, Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Pancreatic exocrine insufficiency

Interventions
This is an open-label single-arm, multicenter Phase I study testing a new CREON formulation of Pancreas Powder gastro-resistant pellets in the clinic of existing patients with cystic fibrosis (CF) who suffer from pancreatic exocrine insufficiency (PEI) and meet eligibility criteria. The study will begin with a one-week Run-in period when participants will continue using their standard PERT treatment with CREON capsules provided by the sponsor. After that week, study participants will be enrolled into the study (Visit 2) and administer CREON new formulation in a dose-comparable manner for one week until Visit 3. Treatment will be administered per oral (PO) per meal/snack for 7 days. A final follow-up telephone call will be scheduled one week after Visit 3. CREON capsules are available in different dosage strengths, depending on the country.

However, patients often require treatment with high doses. As capsule shell volume and the availability of highly active starting material used in the active substance production, currently limit high-strength capsule doses, subjects have no alternative than to take multiple, rather large capsules several times a day which is perceived as inconvenient by some subjects. Participants will be instructed to record the date, time, dose of CREON administered, number of capsules / new formulation, circumstance of use, location of use as well as clinical symptoms, averse-event occurrence, use of medication for acute conditions (e.g. headache), as well as local tolerability throughout the medication period in a paper-based diary. At the end of the treatment, patients will be answering a questionnaire which will help to know about the acceptability of the new formulation.

Intervention Type
Drug

Pharmaceutical study type(s)
Therapy, Others (Acceptability)

Phase
Phase I

Drug/device/biological/vaccine name(s)
Creon [Pancreatin (pancreas powder, pancrelipase), an extract from porcine pancreas glands containing lipolytic, amylolytic and proteolytic activity], Creon Capsules [Multienzymes (amylase, lipase, protease), Multienzyme]

Primary outcome measure
Acceptability of study treatment assessed at Visit 3 (Day 8) with a questionnaire (using an 11-point scale) containing 12 questions on handling, taste and convenience of taking the dose

Secondary outcome measures
1. Lipase dose and number of capsule/new formulation used, recorded in daily diary during the treatment period
2. Switch potential, measured using a questionnaire at Visit 3 (Day 8)
3. Clinical symptoms (stool frequency, stool consistency, abdominal pain and flatulence), recorded as a number or score in a daily diary during the treatment period
4. Adverse events and local tolerability (stomatitis, oral mucosal irritation, bleeding and ulcer assessed by investigator, pain in mouth assessed by subject) during the treatment period

Overall study start date
10/09/2023

Completion date
30/03/2025

Eligibility

Key inclusion criteria
1. Male and female subjects of any ethnic origin
2. At least 18 years of age
3. Cystic fibrosis (documented by two sweat tests or by gene analysis)

4. On treatment with PERT with CREON capsules on the current dose for at least 4 weeks before entry in the study and with satisfactory symptom control (e.g. stool frequency and consistency, meteorism/flatulence, abdominal pain) with a dose of at least two CREON capsules per main meal
5. Willing to comply with the requirements of the study protocol
6. Written informed consent

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
up to 120

Key exclusion criteria
1. Evidence of severe disease, or any other relevant condition (other than CF) as revealed by history or physical examination which might limit participation in or completion of the study
2. History of allergic reaction or hypersensitivity to pancreatin or excipients of CREON (e.g. lipase, amylase, protease, dimethicone, gelatin, xanthan gum, citric acid, red colorant), or any porc or pig product)
3. Known predisposition to allergies
4. Positive β-human chorionic gonadotropin (HCG) pregnancy test, established pregnancy, or breast-feeding at Visit V1. Women of childbearing potential not using at least one effective method of contraception (preferably one whose effectiveness is not dependent on the user, such as an intrauterine device or implant).
5. Women on oral hormonal contraceptives or vaginal ring must agree to use another non-hormonal acceptable highly effective method of contraception in addition to the oral hormonal contraception or vaginal ring
6. Clinically relevant acute infections, febrile disease, or any acute condition (illness) two weeks prior to Visit 1 (V1), as judged by the investigator
7. Lack of suitability for the study:
7.1. History of alcohol or drug abuse within the last 2 years
7.2. Exposure to another investigational product within the last three months
8.0. Administrative reasons:
8.1. Lack of willingness to have personal study-related data collected, archived or
8.2. Transmitted according to protocol 9.3. Lack of willingness or inability to co-operate adequately
8.4. Anticipated non-availability for study visits/procedures
8.5. Vulnerable subjects (such as persons kept in detention)
8.6. Lack of ability or willingness to give informed consent

Date of first enrolment
30/09/2024

Date of final enrolment
30/11/2024

Locations

Countries of recruitment
Germany

United Kingdom

Study participating centre
-
United Kingdom
-

Sponsor information

Organisation
Viatris

Sponsor details
Meda Pharma GmbH & Co. KG (A Viatris Company), Benzstrasse 1
Bad Homburg
Germany
D-61352
None provided
EUClinicalTrials@viatris.com

Sponsor type
Industry

Website
https://www.viatris.com/en

ROR
https://ror.org/01g1gvr46

Funder(s)

Funder type
Industry

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

Results and Publications

Publication and dissemination plan
1. Peer reviewed scientific journals
2. Internal report
3. Conference presentation
4. Publication on website
5. Submission to regulatory authorities

Only anonymised data will be used for publications and conference presentations. Clinical trial teams will be informed of the outcome of the study by providing publicly available materials (publication, presentation, etc.)

Intention to publish date
28/06/2025

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are not expected to be made available during the study conduct, but likely after the study completion due to the Sponsor’s ownership of intellectual property and plans to analyse the data after the dataset completion.

IPD sharing plan summary
Not expected to be made available