# Clinical trial results:
# Randomized, double blind, placebo-controlled trial of Creon in patients with low faecal pancreatic elastase

## Summary

| | |
|---|---|
| EudraCT number | 2011-006019-73 |
| Trial protocol | GB |
| Global end of trial date | 22 May 2015 |

**Results information**

| | |
|---|---|
| Result version number | v1 (current) |
| This version publication date | 12 May 2019 |
| First version publication date | 12 May 2019 |
| Summary attachment (see zip file) | final report (STH16190 FINAL REPORT.pdf) |

## Trial information

**Trial identification**

| | |
|---|---|
| Sponsor protocol code | STH16190 |

**Additional study identifiers**

| | |
|---|---|
| ISRCTN number | - |
| ClinicalTrials.gov id (NCT number) | NCT01865695 |
| WHO universal trial number (UTN) | - |

Notes:

**Sponsors**

| | |
|---|---|
| Sponsor organisation name | Sheffield Teaching Hospitals NHS Foundation Trust |
| Sponsor organisation address | Of Trust Headquarters, 8 Beech Hill Road, Sheffield, United Kingdom, S10 2SB |
| Public contact | Dipak Patel, Sheffield Teaching Hospitals NHS Foundation Trust, ResearchAdministration@sth.nhs.uk |
| Scientific contact | Dipak Patel, Sheffield Teaching Hospitals NHS Foundation Trust, ResearchAdministration@sth.nhs.uk |

Notes:

**Paediatric regulatory details**

| | |
|---|---|
| Is trial part of an agreed paediatric investigation plan (PIP) | No |
| Does article 45 of REGULATION (EC) No 1901/2006 apply to this trial? | No |
| Does article 46 of REGULATION (EC) No 1901/2006 apply to this trial? | No |

Notes:

## Results analysis stage

| | |
|---|---|
| Analysis stage | Final |
| Date of interim/final analysis | 22 May 2015 |
| Is this the analysis of the primary completion data? | Yes |
| Primary completion date | 22 May 2015 |
| Global end of trial reached? | Yes |
| Global end of trial date | 22 May 2015 |
| Was the trial ended prematurely? | Yes |

Notes:

## General information about the trial

Main objective of the trial:

What is the effect of Creon in patients with low faecal pancreatic elastase?

1) Creon being the IMP we propose to evaluate in this study.
2) Low faecal pancreatic elastase being a marker of pancreatic insufficiency

Protection of trial subjects:

No measures in place as events deemed this unnecessary

Background therapy:

Creon is a pancreatic enzyme supplement used in patients with low faecal pancreatic elastase. The study aimed to assess the impact of creon on quality of life

Evidence for comparator:

no comparators were used

| | |
|---|---|
| Actual start date of recruitment | 01 November 2012 |
| Long term follow-up planned | No |
| Independent data monitoring committee (IDMC) involvement? | No |

Notes:

## Population of trial subjects

### Subjects enrolled per country

| | |
|---|---|
| Country: Number of subjects enrolled | United Kingdom: 2 |
| Worldwide total number of subjects | 2 |
| EEA total number of subjects | 2 |

Notes:

### Subjects enrolled per age group

| | |
|---|---|
| In utero | 0 |
| Preterm newborn - gestational age < 37 wk | 0 |
| Newborns (0-27 days) | 0 |
| Infants and toddlers (28 days-23 months) | 0 |
| Children (2-11 years) | 0 |
| Adolescents (12-17 years) | 0 |
| Adults (18-64 years) | 2 |

| | |
|---|---|
| From 65 to 84 years | 0 |
| 85 years and over | 0 |

## Subject disposition

### Recruitment

Recruitment details:

recruitment period 05/12/2012 - 30/11/2014
2 recruited initially but subsequently excluded

### Pre-assignment

Screening details:

not applicable

### Period 1

| | |
|---|---|
| Period 1 title | overall trial period (overall period) |
| Is this the baseline period? | Yes |
| Allocation method | Randomised - controlled |
| Blinding used | Double blind |
| Roles blinded | Subject, Investigator |

### Arms

| | |
|---|---|
| **Arm title** | creon |

Arm description:

Active treatment will be 2 capsules of Creon 25,000 units three times per day and the placebo will be 2 capsules three times per day; for 6 weeks treatment overall

| | |
|---|---|
| Arm type | Experimental |
| Investigational medicinal product name | creon |
| Investigational medicinal product code | 00032-1224 |
| Other name | |
| Pharmaceutical forms | Capsule |
| Routes of administration | Oral use |

Dosage and administration details:

2 capsules of Creon 25,000 units three times per day

| | |
|---|---|
| Investigational medicinal product name | Placebo |
| Investigational medicinal product code | n/a |
| Other name | |
| Pharmaceutical forms | Capsule |
| Routes of administration | Oral use |

Dosage and administration details:

2 capsules three times per day

| **Number of subjects in period 1** | creon |
|---|---|
| Started | 2 |
| Completed | 0 |
| Not completed | 2 |
| Protocol deviation | 2 |

## Baseline characteristics

| Reporting groups | |
|---|---|
| Reporting group title | creon |
| Reporting group description: | |
| Active treatment will be 2 capsules of Creon 25,000 units three times per day and the placebo will be 2 capsules three times per day; for 6 weeks treatment overall | |

| Reporting group values | creon | Total | |
|---|---|---|---|
| Number of subjects | 2 | 2 | |
| Age categorical | | | |
| Units: Subjects | | | |
| Adults (18-64 years) | 2 | 2 | |
| Age continuous | | | |
| Units: years | | | |
| arithmetic mean | 55 | | |
| full range (min-max) | 18 to 64 | - | |
| Gender categorical | | | |
| Units: Subjects | | | |
| Female | 0 | 0 | |
| Male | 2 | 2 | |

## End points

### End points reporting groups

| | |
|---|---|
| Reporting group title | creon |

Reporting group description:

Active treatment will be 2 capsules of Creon 25,000 units three times per day and the placebo will be 2 capsules three times per day; for 6 weeks treatment overall

### Primary: stool frequency

| | |
|---|---|
| End point title | stool frequency[1] |

End point description:

Effect of Creon on stool frequency in patients with low faecal pancreatic elastase following six weeks of treatment

| | |
|---|---|
| End point type | Primary |

End point timeframe:

6 weeks

Notes:

[1] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: no participants completed this study, no data collected, therefore no analysis could take place.

| End point values | creon | | | |
|---|---|---|---|---|
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 0[2] | | | |
| Units: 6 weeks | | | | |

Notes:

[2] - no data as all participants withdrawn from study

### Statistical analyses

No statistical analyses for this end point

## Adverse events

| Adverse events information[1] | |
|---|---|
| Timeframe for reporting adverse events: 6 weeks | |
| Assessment type | Systematic |
| **Dictionary used** | |
| Dictionary name | MedDRA |
| Dictionary version | 5.0 |

Frequency threshold for reporting non-serious adverse events: 5 %

Notes:

[1] - There are no non-serious adverse events recorded for these results. It is expected that there will be at least one non-serious adverse event reported.
Justification: no adverse events recorded as no participants proceeded in study

## More information

### Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

| Date | Amendment |
|---|---|
| 04 October 2013 | Patient Symptom Diary added to study documentation to replace Symptom Questionnaire that was originally approved by REC. The symptom diary is a validated tool which collects data on the primary and secondary endpoints more completely than the previous symptom questionnaire. The Protocol was amended to fully and consistently document when the patient diary is to be completed at baseline and follow up. This exclusion criterion was added on advice of NHS REC. This change was previously approved by REC but MHRA was not previously notified as it was considered that this change was non-substantial for submission to MHRA as it did not significantly affect the scientific integrity or safety of the trial. The exclusion criteria added related to Patients who are unable to speak or understand English. |

Notes:

### Interruptions (globally)

Were there any global interruptions to the trial? No

### Limitations and caveats

Limitations of the trial such as small numbers of subjects analysed or technical problems leading to unreliable data.

2 participants were recruited however they were then excluded as they were not followed up in line with the protocol. The study team then chose to cancel the study due to difficulties with recruitment. Therefore no data has been added to this report.

Notes: