



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
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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
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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
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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
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Dictionary used

Dictionary name	MedDRA
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Dictionary version	5.0
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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: