Final Study Report: Date 22/05/2015

GENERAL STUDY INFORMATION		
STH ref:	16190	
NIHR CSP ref:	N/A	
REC ref:	12/YH/0445	
MHRA ref:	CTA No: 21304/0245/001-0001	EudraCT No: 2011-006019-73
Study title:	Randomized, double blind, placebo-controlled trial of Creon in patients with low faecal pancreatic elastase	
Chief Investigator:	Professor David Sanders	
Principal Investigator:	Dr Matthew Kurien	
Sponsor:	Sheffield Teaching Hospitals NHS Foundation Trust	

Authorisation Date: 05/12/2012

Proposed End Date: 01/11/2015

Actual End Date: 30/11/2014

Study Objective: To determine the effect of Creon in patients with low faecal pancreatic elastase on influencing quality of life, gastrointestinal symptoms and body mass index.

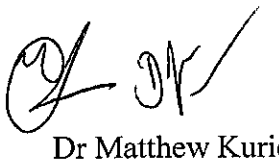
Abstract of study: Faecal elastase is an enzyme test used to identify the presence of pancreatic exocrine insufficiency. This condition manifests with symptoms of diarrhoea, weight loss, causing potential impairment on an individual's quality of life. Creon, a pancreatic enzyme supplement, marketed by Abbott Laboratories, Inc. is currently the standard treatment for this condition. To date, there has been limited work evaluating the merits of this medication in this condition. This study aimed to evaluate the benefits that Creon had in patients with low faecal pancreatic elastase by randomising patients with low faecal pancreatic elastase (<200 μg/g) to either treatment with Creon or placebo. Outcome measures that we aimed assessed were evaluation of stool frequency, abdominal pain, body mass index (BMI) and quality of life.

Planned recruitment Numbers: 50 patients

Actual Outcomes: Two patients were initially recruited into this study. These patients were subsequently excluded, as they were not followed up in accordance with the study protocol. This was highlighted in a sponsor-led monitoring visit in September 2013. Subsequently no further patients were recruited. Following a study management team meeting in November 2014, a decision was made to end the study early, due to difficulties recruiting patients into this study.

Safety Evaluation: No adverse events were reported

Conclusion. Difficulties in recruitment led to the early termination of this study. There are no future plans to undertake further studies evaluating Creon.

Signed: 

Name: Dr Matthew Kurien Professor David S Sanders

Date: 22/05/2015