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 BERLIN-CHEMIE MENARINI	EudraCT Number:	2005-000562-38
	Trial Number:	BCBe/03/Pan-CPI/002
Synopsis of the Clinical Trial Report		

Pancreatin in patients with pancreatic exocrine insufficiency

1 Study Synopsis

Clinical Trial Number: BCBe/03/Pan-CPI/002

Sponsor's Responsible Persons: [REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]

Test Drug: gastro-resistant film-coated tablet with porcine pancreatin (in Germany in trade as Mezym F®)

Dose: 4 gastro-resistant film-coated tablets with porcine pancreatin with a total minimum activity of 40.000 Ph.Eur. units lipase, 30.000 Ph.Eur. units amylase, 1.500 Ph.Eur. units protease.

Active ingredient: pancreatin

Mode of administration: oral

Dose: 4 tablets for 1 single administration

Batch no.: 33008

Comparator Drug: matching Placebo

Dose: 4 gastro-resistant film-coated placebo tablets.

Batch no.: 101203

Indication Studied: Pancreatic exocrine insufficiency due to chronic pancreatitis

Clinical Trial Phase: Phase IV

Number of Patients: Planned: 20 evaluable patients
Analyzed: 14 patients after study discontinuation

(study was discontinued because in a parallel performed similar study the used screening elastase testing showed false positive results, hence the efficacy of the test product was not significant)

Enrolment of First Patient: 06.01.2005

Last Visit of Last Patient: 20.07.2005

Date of Early Termination The study was prematurely discontinued on 31.10.05

Duration of Treatment for Each Patient: 2 single applications separated by a wash-out phase of three days (cross-over design vs. placebo)

9-19 days

Number of Clinical Trial Centers: 3 centres in Ger and CZ

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Coordinating Investigator:

[REDACTED]

Investigators:

[REDACTED]

Objectives / Criteria for evaluation (efficacy and safety)

Primary objective:

- To evaluate the difference between ¹³C-exhalation (in terms of cumulative percentage of ¹³C-dose exhaled per hour after 6 hours starting with the end of the test meal) as a marker of lipid digestion and absorption during treatment with verum and placebo.

Secondary objective(s):

- Difference between the maximum percentage of ¹³C-dose exhaled per hour within 8 hours during treatment with verum and placebo.
 - Difference between ¹³C-exhalation (in terms of cumulative percentage of ¹³C-dose exhaled per hour in 1h-intervals, for 8 hours) during treatment with verum and placebo.
 - Safety and tolerability of trial medication versus placebo (vital signs, laboratory parameters, physical examinations, ECG, Adverse Events).
- Methodology**
- Standardised ¹³C-mixed triglyceride breath test performed twice with patients with known and documented pancreatic exocrine insufficiency, once with verum, once with placebo in a randomised double blind cross-over design.
 - Collection of breath samples before and every 30 min for 8 hours after ingestion of a test meal with ¹³C-mixed triglycerides, additional standardised meal allowed after 6.5 h.
 - Trial medication should be taken unchewed in the middle of the test meal at 08:00 +/- 2 hrs.
 - Measurement of ¹³C-concentration in all breath samples by isotope-selective non-dispersive infrared spectrometry.
 - Documentation of Adverse Events by the investigator.

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Diagnosis and main inclusion criteria

1. Chronic pancreatitis documented by a score of 4 or more added-up using the following scoring system (modified according to Layer et al. (1994)):
2. Faecal elastase 1 test result < 100 µg/g faeces at Screening.

Statistical method

The primary objective of the double blind, randomised cross-over trial is to confirm the superiority of the trial drug versus placebo with regard to the difference in ¹³C-exhalation (in terms of cumulative percentage of ¹³C-dose exhaled per hour after 6 hours starting with the end of the test meal). The difference in ¹³C-exhalation will be assessed by an Analysis of Covariance (or similar non-parametric approaches).

summary conclusions

Efficacy results

Due to the premature discontinuation of the study only 14 patients instead of 20 patients were enrolled. Superiority of Mezym F® vs. placebo could not be shown for the primary efficacy parameter. All data were listed but the planned statistical tests were not performed. At visit 4 after 6h the CO₂ in the placebo group was 3,25% and in the Pancreatin group 3,14 and at Visit 5 for the placebo group 3,11 and for the pancreatin group 3,26.

Safety results

No SAE occurred during the course of the trial. No remarkable changes in vital signs, ECG or physical findings occurred during the trial. the evaluation of routine laboratory examination, physical examinations, ECG recordings and measurement of vital signs (blood pressure, pulse rate and body weight) revealed that administration of gastro-resistant film-coated tablet with porcine pancreatin (in Germany in trade as Mezym F®) was well tolerated and safe.