Trial record **1 of 1** for: VIO16EPI07-01

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Safety and Efficacy Study of Viokase® 16 for the Correction of Steatorrhea

The safety and scientific validity of this study is the responsibility of the study sponsor and investigators. Listing a study does not mean it has been evaluated by the U.S. Federal Government. Read our disclaimer for details.

ClinicalTrials.gov Identifier: NCT00559364

Recruitment Status : Completed
First Posted : November 16, 2007
Results First Posted : March 12, 2014
Last Update Posted : March 16, 2017

Sponsor:
Forest Laboratories

Information provided by (Responsible Party):
Forest Laboratories

Study Details | Tabular View | Study Results | Disclaimer
How to Read a Study Record

Study Type:	Interventional

Study Design:	Allocation: Randomized; Intervention Model: Parallel Assignment; Masking: Double (Participant, Investigator); Primary Purpose: Treatment
Conditions:	Exocrine Pancreatic Insufficiency Chronic Pancreatitis Pancreatectomy
Interventions:	Drug: Viokase® 16 Drug: Placebo Drug: Proton pump inhibitor (PPI) Drug: Omeprazole

Participant Flow

Hide Participant Flow

Recruitment Details

Key information relevant to the recruitment process for the overall study, such as dates of the recruitment period and locations
No text entered.

Pre-Assignment Details

Significant events and approaches for the overall study following participant enrollment, but prior to group assignment
Patients underwent screening phase (up to 10 days) and wash-out phase (6 to 7 days, where baseline coefficient of fat absorption [CFA] was determined) before entering randomization phase. Out of 218 patients, who entered screening and washout phases, 168 discontinued due to screen failure; 50 patients were randomized to treatment phase.

Reporting Groups

	Description
Viokase®	Patients received Viokase® 16, 22 tablets orally daily (that is, 6 tablets per meal and 2 tablets with 2 of 3 snacks) for 6 to 7 days in treatment phase. Patients on proton pump inhibitor (PPI) therapy during Screening continued their usual (those not using

	PPI therapy at screening received omeprazole 20 milligram orally once daily) throughout the study.
Placebo	Patients received matching placebo, 22 tablets orally daily (that is, 6 tablets per meal and 2 tablets with 2 of 3 snacks) for 6 to 7 days in treatment phase. Patients on proton pump inhibitor (PPI) therapy during Screening continued their usual (those not using PPI therapy at screening received omeprazole 20 milligram orally once daily) throughout the study.

Participant Flow: Overall Study

	Viokase®	Placebo
STARTED	**30**	**20**
COMPLETED	**29**	**20**
NOT COMPLETED	**1**	**0**
Inclusion/exclusion criteria failure	**1**	**0**

Baseline Characteristics

Hide Baseline Characteristics

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Intent-to-treat (ITT) population included all randomized patients.

Reporting Groups

	Description
Viokase®	Patients received Viokase® 16, 22 tablets orally daily (that is, 6 tablets per meal and 2 tablets with 2 of 3 snacks) for 6 to 7 days in treatment phase. Patients on proton pump inhibitor (PPI) therapy during Screening continued their usual (those not using PPI therapy at screening received omeprazole 20 milligram orally once daily) throughout the study.

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Total	Total of all reporting groups

Baseline Measures

	Viokase®	**Placebo**	**Total**
Overall Participants Analyzed [Units: Participants]	**30**	**20**	**50**
Age [Units: Years] Mean (Standard Deviation)	**50.9 (9.91)**	**50.6 (7.63)**	**50.8 (8.98)**
Sex: Female, Male [Units: Participants] Count of Participants			
Female	**8** 26.7%	**1** 5.0%	**9** 18.0%
Male	**22** 73.3%	**19** 95.0%	**41** 82.0%

Outcome Measures

Hide All Outcome Measures

1. **Primary: Percent Coefficient of Fat Absorption (CFA) [Time Frame: Day 1 up to Day 4 or Day 5 in inpatient period of treatment phase]**

Measure Type	Primary
Measure Title	Percent Coefficient of Fat Absorption (CFA)
Measure Description	Percent CFA was calculated as ([fat intake - fat excretion]/fat intake)*100, determined in the stools which was collected from Day 1 to Day 4 or Day 5 during the inpatient period of treatment phase. Mean percent (%) CFA

	was calculated for Day 1 to Day 4 or Day 5 in inpatient period of treatment phase.
Time Frame	Day 1 up to Day 4 or Day 5 in inpatient period of treatment phase

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Intent-to-treat (ITT) population included all randomized patients. Missing values at treatment phase were imputed using the median (50th percentile) of all non-missing values within a treatment group.

Reporting Groups

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Measured Values

	Viokase®	**Placebo**
Participants Analyzed [Units: Participants]	**30**	**20**
Percent Coefficient of Fat Absorption (CFA) [Units: Percent CFA] Mean (Standard Deviation)	**85.52 (8.902)**	**58.02 (24.249)**

Statistical Analysis 1 for Percent Coefficient of Fat Absorption (CFA)

Groups [1]	All groups
Statistical Test Type [2]	Superiority or Other
Statistical Method [3]	ANCOVA
P Value [4]	<0.0001

[1] Additional details about the analysis, such as null hypothesis and power calculation:

Analysis of covariance (ANCOVA) model using treatment group and pooled site as fixed effects and wash-out phase CFA% value as covariate was used.

[2] Details of power calculation, definition of non-inferiority margin, and other key parameters:

No text entered.

[3] Other relevant method information, such as adjustments or degrees of freedom:

No text entered.

[4] Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:

No text entered.

2. Secondary: Mean Daily Number of Stools [Time Frame: Day 1 up to Day 4 or Day 5 in inpatient period of treatment phase]

Measure Type	Secondary
Measure Title	Mean Daily Number of Stools
Measure Description	Mean daily number of stools of each patient was calculated from frequency of stools by the patient per day. Mean daily number of stools during the collection period (Day 1 to Day 4 or Day 5 in inpatient period of treatment phase) for total patients was summarized.
Time Frame	Day 1 up to Day 4 or Day 5 in inpatient period of treatment phase

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
ITT population included all randomized patients.

Reporting Groups

	Description
Viokase®	Patients received Viokase® 16, 22 tablets orally daily (that is, 6 tablets per meal and 2 tablets with 2 of 3 snacks) for 6 to 7 days in treatment phase. Patients on proton pump inhibitor (PPI) therapy during Screening continued their usual (those not using PPI therapy at screening received omeprazole 20 milligram orally once daily) throughout the study.
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Measured Values

	Viokase®	**Placebo**
Participants Analyzed [Units: Participants]	**30**	**20**
Mean Daily Number of Stools [Units: Stools per day] Mean (Standard Deviation)	**1.93 (0.989)**	**2.33 (0.950)**

No statistical analysis provided for Mean Daily Number of Stools

3. Secondary: Percentage of Stools Categorized as Per Consistency [Time Frame: Day 1 up to Day 4 or Day 5 in inpatient period of treatment phase]

Measure Type	Secondary

Measure Title	Percentage of Stools Categorized as Per Consistency
Measure Description	Stool consistency was categorized as hard, formed/normal, soft and watery. Percentage of stools of a specific consistency for each patient was calculated as: (total number of stools of specific consistency during the completed days of the inpatient period/ total number of stools during the completed days of the inpatient period)*100. Mean percentage of stool categorized as per consistency for total patients was summarized.
Time Frame	Day 1 up to Day 4 or Day 5 in inpatient period of treatment phase

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
ITT population included all randomized patients.

Reporting Groups

	Description
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Measured Values

	Viokase®	**Placebo**
Participants Analyzed [Units: Participants]	**30**	**20**

Percentage of Stools Categorized as Per Consistency [Units: Percentage of stools] Mean (Standard Deviation)		
Hard stools	**5.08 (13.61)**	**0.67 (2.98)**
Formed/normal stools	**45.86 (33.27)**	**37.23 (37.91)**
Soft stools	**47.80 (33.31)**	**55.48 (39.46)**
Watery stools	**1.26 (4.82)**	**5.80 (14.57)**

No statistical analysis provided for Percentage of Stools Categorized as Per Consistency

Serious Adverse Events

Hide Serious Adverse Events

Time Frame	Day 1 of treatment phase up to 30 days after last dose administration
Additional Description	Adverse event (AE) was any untoward medical occurrence regardless of causal relationship to study drug. Serious AE was any event that resulted in death, life threatening, required or prolonged in-patient hospitalization, significant disability/incapacity, or was a congenital anomaly/birth defect or is assessed as important medical event.

Reporting Groups

	Description
Viokase®	Patients received Viokase® 16, 22 tablets orally daily (that is, 6 tablets per meal and 2 tablets with 2 of 3 snacks) for 6 to 7 days in treatment phase. Patients on proton pump inhibitor (PPI) therapy during Screening continued their usual (those not using PPI therapy at screening received omeprazole 20 milligram orally once daily) throughout the study.
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Serious Adverse Events

	Viokase®	Placebo
Total, Serious Adverse Events		
# participants affected / at risk	**2/30 (6.67%)**	**0/20 (0.00%)**
Cardiac disorders		
Cardiac failure * 1		
# participants affected / at risk	**1/30 (3.33%)**	**0/20 (0.00%)**
General disorders		
Disease progression * 1		
# participants affected / at risk	**1/30 (3.33%)**	**0/20 (0.00%)**
Hepatobiliary disorders		
Cholelithiasis * 1		
# participants affected / at risk	**1/30 (3.33%)**	**0/20 (0.00%)**
Investigations		
Coagulation factor decreased * 1		
# participants affected / at risk	**1/30 (3.33%)**	**0/20 (0.00%)**
Respiratory, thoracic and mediastinal disorders		
Pulmonary oedema * 1		
# participants affected / at risk	**1/30 (3.33%)**	**0/20 (0.00%)**

* Events were collected by non-systematic assessment

1 Term from vocabulary, MedDRA (11.1)

Other Adverse Events

Hide Other Adverse Events

Time Frame	Day 1 of treatment phase up to 30 days after last dose administration
Additional Description	

	Adverse event (AE) was any untoward medical occurrence regardless of causal relationship to study drug. Serious AE was any event that resulted in death, life threatening, required or prolonged in-patient hospitalization, significant disability/incapacity, or was a congenital anomaly/birth defect or is assessed as important medical event.

Frequency Threshold

Threshold above which other adverse events are reported	0%

Reporting Groups

	Description
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Other Adverse Events

	Viokase®	Placebo
Total, Other (not including serious) Adverse Events		
# participants affected / at risk	**7/30 (23.33%)**	**2/20 (10.00%)**
Blood and lymphatic system disorders		
Anaemia * 1		
# participants affected / at risk	**1/30 (3.33%)**	**0/20 (0.00%)**
Gastrointestinal disorders		
Anal pruritus * 1		
# participants affected / at risk	**2/30 (6.67%)**	**0/20 (0.00%)**
Abdominal pain * 1		

# participants affected / at risk	1/30 (3.33%)	0/20 (0.00%)
Ascites * 1		
# participants affected / at risk	1/30 (3.33%)	0/20 (0.00%)
Flatulence * 1		
# participants affected / at risk	1/30 (3.33%)	0/20 (0.00%)
General disorders		
Oedema peripheral * 1		
# participants affected / at risk	1/30 (3.33%)	0/20 (0.00%)
Hepatobiliary disorders		
Bile duct stone * 1		
# participants affected / at risk	1/30 (3.33%)	0/20 (0.00%)
Hydrocholecystis * 1		
# participants affected / at risk	1/30 (3.33%)	0/20 (0.00%)
Infections and infestations		
Viral infection * 1		
# participants affected / at risk	1/30 (3.33%)	0/20 (0.00%)
Musculoskeletal and connective tissue disorders		
Myalgia * 1		
# participants affected / at risk	0/30 (0.00%)	1/20 (5.00%)
Nervous system disorders		
Headache * 1		
# participants affected / at risk	1/30 (3.33%)	0/20 (0.00%)
Renal and urinary disorders		
Renal cyst * 1		
# participants affected / at risk	1/30 (3.33%)	0/20 (0.00%)
Respiratory, thoracic and mediastinal disorders		
Oropharyngeal pain * 1		
# participants affected / at risk	1/30 (3.33%)	1/20 (5.00%)
Skin and subcutaneous tissue disorders		
Rash * 1		

# participants affected / at risk	**1/30 (3.33%)**	**0/20 (0.00%)**

* Events were collected by non-systematic assessment

1 Term from vocabulary, MedDRA (11.1)

Limitations and Caveats

Hide Limitations and Caveats

Limitations of the study, such as early termination leading to small numbers of participants analyzed and technical problems with measurement leading to unreliable or uninterpretable data

Results for percentage of stool characteristics per bowel movement and number of days with at least 1 stool of specific characteristic were not reported due to change in planned analysis.

More Information

Hide More Information

Certain Agreements:

Principal Investigators are **NOT** employed by the organization sponsoring the study.

There **IS** an agreement between Principal Investigators and the Sponsor (or its agents) that restricts the PI's rights to discuss or publish trial results after the trial is completed.

The agreement is:

☐ The only disclosure restriction on the PI is that the sponsor can review results communications prior to public release and can embargo communications regarding trial results for a period that is **less than or equal to 60 days**. The sponsor cannot require changes to the communication and cannot extend the embargo.

☐ The only disclosure restriction on the PI is that the sponsor can review results communications prior to public release and can embargo communications regarding trial results for a period that is **more than 60 days but less than or equal to 180 days**. The sponsor cannot require changes to the communication and cannot extend the embargo.

☑ Other disclosure agreement that restricts the right of the PI to discuss or publish trial results after the trial is completed.

Restriction Description: Restrictions vary in accordance with each agreement with the individual investigators. Sponsor will allow publication but will prohibit disclosure of Sponsor's confidential information within any publication and can defer publication for a period of time to allow for Sponsor to obtain patent or other intellectual property right protection.

Results Point of Contact:

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Responsible Party:	Forest Laboratories
ClinicalTrials.gov Identifier:	NCT00559364 History of Changes
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