ClinicalTrials.gov Protocol and Results Registration System (PRS) Receipt
Release Date: 06/16/2014

# Effects of Lanthanum Carbonate on FGF-23 in Subjects With Stage 3 CKD

This study has been completed.

| | |
|---|---|
| Sponsor: | Shire |
| Collaborators: | |
| Information provided by (Responsible Party): | Shire |
| ClinicalTrials.gov Identifier: | NCT01128179 |

## Purpose

To assess the effects of 12 weeks of treatment with lanthanum carbonate compared with placebo on serum intact Fibroblast Growth Factor 23 (FGF23) levels.

| Condition | Intervention | Phase |
|---|---|---|
| Chronic Kidney Disease | Drug: Lanthanum carbonate<br>Drug: Placebo | Phase 2 |

Study Type: Interventional
Study Design: Treatment, Parallel Assignment, Double Blind (Subject, Investigator), Randomized, Safety/Efficacy Study
Official Title: A Proof of Concept, Phase 2a, Double-blind, Parallel Group, Randomised, Placebo-controlled Study to Assess the Effect of Lanthanum Carbonate on Intact FGF23 in Normo-phosphataemic Subjects With Stage 3 Chronic Kidney Disease

Further study details as provided by Shire:

Primary Outcome Measure:

- Natural Logarithm Transformed Serum Intact Fibroblast Growth Factor (FGF-23) Levels at Week 12 Last Observation Carried Forward (LOCF) [Time Frame: 12 Weeks] [Designated as safety issue: No]

FGF-23 plays an important role in mineral metabolism in chronic kidney disease patients. It is secreted by bone cells in response to hyperphosphatemia. It acts to decrease renal phosphate reabsorption. Administration of a phosphate-binder (i.e. lanthanum carbonate) was expected to produce a reduction in FGF-23 levels.

Secondary Outcome Measures:

- Change From Baseline in Serum Intact Parathyroid Hormone (iPTH) Values at Week 12 (LOCF) [Time Frame: 12 Weeks] [Designated as safety issue: Yes]
- Change From Baseline in 1,25-Dihydroxy Vitamin D Values at Week 12 (LOCF) [Time Frame: 12 weeks] [Designated as safety issue: Yes]
- Change From Baseline in Urinary Fractional Excretion of Phosphate Values at Week 12 (LOCF) [Time Frame: 12 weeks] [Designated as safety issue: Yes]
- Change From Baseline in Serum Phosphate Values at Week 12 (LOCF) [Time Frame: 12 weeks] [Designated as safety issue: Yes]
- Change From Baseline in Serum Total Calcium Values at Week 12 (LOCF) [Time Frame: 12 weeks] [Designated as safety issue: Yes]
- Change From Baseline in Calcium-Phosphate Product Values at Week 12 (LOCF) [Time Frame: 12 weeks] [Designated as safety issue: Yes]

Enrollment: 35
Study Start Date: November 2010
Primary Completion Date: May 2012
Study Completion Date: May 2012

| Arms | Assigned Interventions |
|---|---|
| Experimental: Lanthanum carbonate | Drug: Lanthanum carbonate<br>1000 mg in chewable tablets administered three times a day (for a total of 3000 mg/day) for 12 weeks<br><br>Other Names:<br>Fosrenol/Foznol |
| Placebo Comparator: Placebo | Drug: Placebo<br>Matching placebo chewable tablets administered 3 times a day for 12 weeks |

## Eligibility

Ages Eligible for Study: 18 Years and older
Genders Eligible for Study: Both
Accepts Healthy Volunteers: No

### Criteria

Inclusion Criteria:

Subjects meeting all of the criteria listed below may be included in the study:

1. ≥18 years old.
2. Male, or non-pregnant, non-lactating females who agree to comply with any applicable contraceptive requirements of the protocol.
3. Been in the care of a physician for CKD for >2 months, and are not expected to begin dialysis for at least 6 months.
4. Screening serum c-terminal FGF23 > 50.0RU/mL.

5. Screening estimated glomerular filtration rate (eGFR) of 30-59mL/min/1.73m2 using the MDRD formula.
6. Normal serum phosphate (0.808-1.55mmol/L).
7. Endogenous 25-hydroxy Vitamin D levels >20ng/mL.
8. Adequate protein diet (includes 2-3 portions of protein-rich food per day).
9. An understanding, ability, and willingness to fully comply with study procedures and restrictions.
10. Ability to provide written, signed, and dated (personally) informed consent to participate in the study.

Exclusion Criteria

1. Vitamin D supplementation required.
2. Compounds containing calcium, phosphate, aluminium or magnesium required.
3. Acute renal failure.
4. Rapidly progressing glomerulonephritis.
5. Vegetarian diet.
6. Known allergy to iodine.
7. Clinically significant uncontrolled concurrent illness, which, in the opinion of the Investigator, would impair subjects' ability to give informed consent or take part in or complete this clinical study.
8. Cirrhosis or other clinically significant liver disease (aspartate transaminase (AST) or alanine transaminase (ALT) >3 times the upper limit of normal or bilirubin >2 times the upper limit of normal).
9. Past (treated within the last 5 years) or present GI disorders including uncontrolled peptic ulcer, Crohn's disease (or other conditions where the integrity of the GI tract may be compromised), malignancy, or GI bleed within the last 6 months.
10. Life-threatening malignancy or current multiple myeloma.
11. Known to be Human Immunodeficiency Virus (HIV) positive.
12. History of poor compliance with diet or medication that in the Investigator's opinion may interfere with adherence to the protocol.
13. History of alcohol or other substance abuse within 6 months prior to screening.
14. Subjects must not have used another investigational medicinal product or taken part in a clinical trial within the last 30 days prior to enrolment.
15. Subjects who have previously been enrolled into this study and subsequently withdrawn.

## Contacts and Locations

Locations

France

Dr Pablo Urena Torres

Saint Ouen, Paris, France, 93400

## More Information

Results Publications:

Pablo Ureña-Torres, Dominique Prié, Karim Keddad, Peter Preston, Paul Wilde, Hong Wan and J Brian Copley. Changes in fibroblast growth factor 23 levels in normophosphatemic patients with chronic kidney disease stage 3 treated with lanthanum carbonate: results of the PREFECT study, a phase 2a, double blind, randomized, placebo-controlled trial. BMC Nephrology 2014, 15:71

Responsible Party: Shire
Study ID Numbers: SPD405-703

# Study Results

## Participant Flow

Reporting Groups

| | Description |
|---|---|
| Lanthanum Carbonate | 1000 mg in chewable tablets (given as 2 x 500 mg tablets) administered three times a day (for a total of 3000 mg/day) for 12 weeks |
| Placebo | Matching placebo chewable tablets administered 3 times a day for 12 weeks |

Overall Study

| | Lanthanum Carbonate | Placebo |
|---|---|---|
| Started | 23 | 12 |
| Completed | 21 | 12 |
| Not Completed | 2 | 0 |
| Death | 1 | 0 |
| Protocol Violation | 1 | 0 |

## Baseline Characteristics

Analysis Population Description

The Safety Analysis Set was defined as all randomized subjects who received at least 1 dose of investigational product. This population was used in all safety reporting.

Reporting Groups

| | Description |
|---|---|
| Lanthanum Carbonate | 1000 mg in chewable tablets (given as 2 x 500 mg tablets) administered three times a day (for a total of 3000 mg/day) for 12 weeks |
| Placebo | Matching placebo chewable tablets administered 3 times a day for 12 weeks |

Baseline Measures

| | Lanthanum Carbonate | Placebo | Total |
|---|---|---|---|
| Number of Participants | 23 | 12 | 35 |
| Age, Continuous<br>[units: years]<br>Mean (Standard Deviation) | 66.0 (13.9) | 69.4 (13.2) | 67.2 (13.6) |
| Age, Customized<br>>=18 years [units: participants] | 23 | 12 | 35 |
| Gender, Male/Female<br>[units: participants] | | | |
| Female | 10 | 7 | 17 |
| Male | 13 | 5 | 18 |
| Region of Enrollment<br>France [units: participants] | 23 | 12 | 35 |

## Outcome Measures

1. Primary Outcome Measure:

| | |
|---|---|
| Measure Title | Natural Logarithm Transformed Serum Intact Fibroblast Growth Factor (FGF-23) Levels at Week 12 Last Observation Carried Forward (LOCF) |
| Measure Description | FGF-23 plays an important role in mineral metabolism in chronic kidney disease patients. It is secreted by bone cells in response to hyperphosphatemia. It acts to decrease renal phosphate reabsorption. Administration of a phosphate-binder (i.e. lanthanum carbonate) was expected to produce a reduction in FGF-23 levels. |
| Time Frame | 12 Weeks |
| Safety Issue? | No |

Analysis Population Description

Per-protocol (PP) set are subjects who received at least 1 dose of investigational product and who had primary data assessment available from Week 2 or later and who did not have pre-defined major protocol deviations that could have affected the primary variable.

Reporting Groups

| | Description |
|---|---|
| Lanthanum Carbonate | 1000 mg in chewable tablets (given as 2 x 500 mg tablets) administered three times a day (for a total of 3000 mg/day) for 12 weeks |
| Placebo | Matching placebo chewable tablets administered 3 times a day for 12 weeks |

Measured Values

| | Lanthanum Carbonate | Placebo |
|---|---|---|
| Number of Participants Analyzed | 17 | 12 |
| Natural Logarithm Transformed Serum Intact Fibroblast Growth Factor (FGF-23) Levels at Week 12 Last Observation Carried Forward (LOCF)<br>[units: pg/ml]<br>Least Squares Mean (Standard Error) | 4.0089 (0.0709) | 4.1210 (0.0844) |

Statistical Analysis 1 for Natural Logarithm Transformed Serum Intact Fibroblast Growth Factor (FGF-23) Levels at Week 12 Last Observation Carried Forward (LOCF)

| | | |
|---|---|---|
| Statistical Analysis Overview | Comparison Groups | Lanthanum Carbonate, Placebo |
| | Comments | Assuming that the natural logarithm transformed serum intact FGF-23 is normally distributed with a mean of 3.5 and a standard deviation of 0.46, 33 subjects randomised 2:1 (lanthanum carbonate to placebo) will be sufficient to detect with 80% power at the 5% 2-sided significance level a decrease of 0.5 in the mean difference (placebo minus lanthanum carbonate) of the log-transformed data at Week 12. |
| | Non-Inferiority or Equivalence Analysis? | No |
| | Comments | [Not specified] |

| | | |
|---|---|---|
| Statistical Test of Hypothesis | P-Value | 0.3186 |
| | Comments | The a priori significance level was 5%. There was no adjustment for multiple comparisons. |
| | Method | ANCOVA |
| | Comments | Not applicable. |

| | | |
|---|---|---|
| Method of Estimation | Estimation Parameter | Mean Difference (Final Values) |
| | Estimated Value | -0.1121 |
| | Confidence Interval | (2-Sided) 95%<br>-0.3389 to 0.1146 |
| | Estimation Comments | [Not specified] |

2. Secondary Outcome Measure:

| | |
|---|---|
| Measure Title | Change From Baseline in Serum Intact Parathyroid Hormone (iPTH) Values at Week 12 (LOCF) |
| Measure Description | |

| | |
|---|---|
| Time Frame | 12 Weeks |
| Safety Issue? | Yes |

Analysis Population Description
PP

Reporting Groups

| | Description |
|---|---|
| Lanthanum Carbonate | 1000 mg in chewable tablets (given as 2 x 500 mg tablets) administered three times a day (for a total of 3000 mg/day) for 12 weeks |
| Placebo | Matching placebo chewable tablets administered 3 times a day for 12 weeks |

Measured Values

| | Lanthanum Carbonate | Placebo |
|---|---|---|
| Number of Participants Analyzed | 17 | 12 |
| Change From Baseline in Serum Intact Parathyroid Hormone (iPTH) Values at Week 12 (LOCF)<br>[units: pg/ml]<br>Least Squares Mean (Standard Error) | 1.67 (3.96) | -4.87 (4.72) |

Statistical Analysis 1 for Change From Baseline in Serum Intact Parathyroid Hormone (iPTH) Values at Week 12 (LOCF)

| | | |
|---|---|---|
| Statistical Analysis Overview | Comparison Groups | Lanthanum Carbonate, Placebo |
| | Comments | The null hypothesis was that there would be no difference between the 2 treatment groups in the mean change from baseline of serum iPTH at Week 12 (LOCF) in an analysis of covariance (ANCOVA) with treatment as a factor and the baseline iPTH as a covariate.<br>The study was not powered for the analysis of this parameter. |
| | Non-Inferiority or Equivalence Analysis? | No |
| | Comments | [Not specified] |

| | | |
|---|---|---|
| Statistical Test of Hypothesis | P-Value | 0.2995 |
| | Comments | The p-value was unadjusted and had no a priori significance level. |
| | Method | ANCOVA |
| | Comments | Not applicable |

| | | |
|---|---|---|
| Method of Estimation | Estimation Parameter | Mean Difference (Final Values) |

| | | |
|---|---|---|
| | Estimated Value | 6.54 |
| | Confidence Interval | (2-Sided) 95%<br>-6.15 to 19.23 |
| | Estimation Comments | [Not specified] |

3. Secondary Outcome Measure:

| | |
|---|---|
| Measure Title | Change From Baseline in 1,25-Dihydroxy Vitamin D Values at Week 12 (LOCF) |
| Measure Description | |
| Time Frame | 12 weeks |
| Safety Issue? | Yes |

Analysis Population Description
PP

Reporting Groups

| | Description |
|---|---|
| Lanthanum Carbonate | 1000 mg in chewable tablets (given as 2 x 500 mg tablets) administered three times a day (for a total of 3000 mg/day) for 12 weeks |
| Placebo | Matching placebo chewable tablets administered 3 times a day for 12 weeks |

Measured Values

| | Lanthanum Carbonate | Placebo |
|---|---|---|
| Number of Participants Analyzed | 17 | 12 |
| Change From Baseline in 1,25-Dihydroxy Vitamin D Values at Week 12 (LOCF)<br>[units: pg/ml]<br>Least Squares Mean (Standard Error) | -1.75 (3.22) | -6.86 (3.85) |

Statistical Analysis 1 for Change From Baseline in 1,25-Dihydroxy Vitamin D Values at Week 12 (LOCF)

| | | |
|---|---|---|
| Statistical Analysis Overview | Comparison Groups | Lanthanum Carbonate, Placebo |
| | Comments | The null hypothesis was that there would be no difference between the 2 treatment groups in the mean change from baseline of 1,25-Dihydroxy Vitamin D at Week 12 (LOCF) when utilizing an analysis of covariance (ANCOVA) with treatment as a factor and the baseline 1,25-Dihydroxy Vitamin D as a covariate.<br><br>The study was not powered for the analysis of this parameter. |

| | | |
|---|---|---|
| | Non-Inferiority or Equivalence Analysis? | No |
| | Comments | [Not specified] |

| | | |
|---|---|---|
| Statistical Test of Hypothesis | P-Value | 0.3252 |
| | Comments | The p-value was unadjusted and had no a priori significance level. |
| | Method | ANCOVA |
| | Comments | Not applicable |

| | | |
|---|---|---|
| Method of Estimation | Estimation Parameter | Mean Difference (Final Values) |
| | Estimated Value | 5.11 |
| | Confidence Interval | (2-Sided) 95%<br>-5.36 to 15.57 |
| | Estimation Comments | [Not specified] |

4. Secondary Outcome Measure:

| | |
|---|---|
| Measure Title | Change From Baseline in Urinary Fractional Excretion of Phosphate Values at Week 12 (LOCF) |
| Measure Description | |
| Time Frame | 12 weeks |
| Safety Issue? | Yes |

Analysis Population Description
PP

Reporting Groups

| | Description |
|---|---|
| Lanthanum Carbonate | 1000 mg in chewable tablets (given as 2 x 500 mg tablets) administered three times a day (for a total of 3000 mg/day) for 12 weeks |
| Placebo | Matching placebo chewable tablets administered 3 times a day for 12 weeks |

Measured Values

| | Lanthanum Carbonate | Placebo |
|---|---|---|
| Number of Participants Analyzed | 17 | 12 |

| | Lanthanum Carbonate | Placebo |
|---|---|---|
| Change From Baseline in Urinary Fractional Excretion of Phosphate Values at Week 12 (LOCF)<br>[units: percentage of excretion of phosphate]<br>Least Squares Mean (Standard Error) | -5.9 (1.5) | -2.2 (1.9) |

Statistical Analysis 1 for Change From Baseline in Urinary Fractional Excretion of Phosphate Values at Week 12 (LOCF)

| | | |
|---|---|---|
| Statistical Analysis Overview | Comparison Groups | Lanthanum Carbonate, Placebo |
| | Comments | The null hypothesis was that there would be no difference between the 2 treatment groups in the mean change from baseline of Urinary Fractional Excretion of Phosphate at Week 12 (LOCF) when utilizing an analysis of covariance (ANCOVA) with treatment as a factor and the baseline Urinary Fractional Excretion of Phosphate as a covariate.<br>The study was not powered for the analysis of this parameter. |
| | Non-Inferiority or Equivalence Analysis? | No |
| | Comments | [Not specified] |

| | | |
|---|---|---|
| Statistical Test of Hypothesis | P-Value | 0.1459 |
| | Comments | The p-value was unadjusted and had no a priori significance level. |
| | Method | ANCOVA |
| | Comments | Not applicable |

| | | |
|---|---|---|
| Method of Estimation | Estimation Parameter | Mean Difference (Final Values) |
| | Estimated Value | -3.7 |
| | Confidence Interval | (2-Sided) 95%<br>-8.845 to 1.403 |
| | Estimation Comments | [Not specified] |

5. Secondary Outcome Measure:

| | |
|---|---|
| Measure Title | Change From Baseline in Serum Phosphate Values at Week 12 (LOCF) |
| Measure Description | |
| Time Frame | 12 weeks |
| Safety Issue? | Yes |

Analysis Population Description
PP

Reporting Groups

| | Description |
|---|---|
| Lanthanum Carbonate | 1000 mg in chewable tablets (given as 2 x 500 mg tablets) administered three times a day (for a total of 3000 mg/day) for 12 weeks |
| Placebo | Matching placebo chewable tablets administered 3 times a day for 12 weeks |

Measured Values

| | Lanthanum Carbonate | Placebo |
|---|---|---|
| Number of Participants Analyzed | 17 | 12 |
| Change From Baseline in Serum Phosphate Values at Week 12 (LOCF)<br>[units: mmol/L]<br>Least Squares Mean (Standard Error) | 0.0053 (0.0371) | 0.0350 (0.0443) |

Statistical Analysis 1 for Change From Baseline in Serum Phosphate Values at Week 12 (LOCF)

| | | |
|---|---|---|
| Statistical Analysis Overview | Comparison Groups | Lanthanum Carbonate, Placebo |
| | Comments | The null hypothesis was that there would be no difference between the 2 treatment groups in the mean change from baseline of Serum Phosphate at Week 12 (LOCF) in an analysis of covariance (ANCOVA) with treatment as a factor and the baseline Serum Phosphate as a covariate.<br>The study was not powered for the analysis of this parameter |
| | Non-Inferiority or Equivalence Analysis? | No |
| | Comments | [Not specified] |

| | | |
|---|---|---|
| Statistical Test of Hypothesis | P-Value | 0.6134 |
| | Comments | The p-value was unadjusted and had no a priori significance level. |
| | Method | ANCOVA |
| | Comments | Not applicable |

| | | |
|---|---|---|
| Method of Estimation | Estimation Parameter | Mean Difference (Final Values) |
| | Estimated Value | -0.0297 |
| | Confidence Interval | (2-Sided) 95% |

| | | |
|---|---|---|
| | | -0.1492 to 0.0897 |
| | Estimation Comments | [Not specified] |

6. Secondary Outcome Measure:

| | |
|---|---|
| Measure Title | Change From Baseline in Serum Total Calcium Values at Week 12 (LOCF) |
| Measure Description | |
| Time Frame | 12 weeks |
| Safety Issue? | Yes |

Analysis Population Description
PP

Reporting Groups

| | Description |
|---|---|
| Lanthanum Carbonate | 1000 mg in chewable tablets (given as 2 x 500 mg tablets) administered three times a day (for a total of 3000 mg/day) for 12 weeks |
| Placebo | Matching placebo chewable tablets administered 3 times a day for 12 weeks |

Measured Values

| | Lanthanum Carbonate | Placebo |
|---|---|---|
| Number of Participants Analyzed | 17 | 12 |
| Change From Baseline in Serum Total Calcium Values at Week 12 (LOCF)<br>[units: mmol/L]<br>Least Squares Mean (Standard Error) | 0.0242 (0.0323) | -0.0052 (0.0385) |

Statistical Analysis 1 for Change From Baseline in Serum Total Calcium Values at Week 12 (LOCF)

| | | |
|---|---|---|
| Statistical Analysis Overview | Comparison Groups | Lanthanum Carbonate, Placebo |
| | Comments | The null hypothesis was that there would be no difference between the 2 treatment groups in the mean change from baseline of Serum Total Calcium at Week 12 (LOCF) in an analysis of covariance (ANCOVA) with treatment as a factor and the baseline Serum Total Calcium as a covariate.<br>The study was not powered for the analysis of this parameter. |
| | Non-Inferiority or Equivalence Analysis? | No |

| | | |
|---|---|---|
| | Comments | [Not specified] |

| | | |
|---|---|---|
| Statistical Test of Hypothesis | P-Value | 0.5636 |
| | Comments | The p-value was unadjusted and had no a priori significance level. |
| | Method | ANCOVA |
| | Comments | Not applicable |

| | | |
|---|---|---|
| Method of Estimation | Estimation Parameter | Mean Difference (Final Values) |
| | Estimated Value | 0.0294 |
| | Confidence Interval | (2-Sided) 95%<br>-0.0739 to 0.1328 |
| | Estimation Comments | [Not specified] |

7. Secondary Outcome Measure:

| | |
|---|---|
| Measure Title | Change From Baseline in Calcium-Phosphate Product Values at Week 12 (LOCF) |
| Measure Description | |
| Time Frame | 12 weeks |
| Safety Issue? | Yes |

Analysis Population Description
PP

Reporting Groups

| | Description |
|---|---|
| Lanthanum Carbonate | 1000 mg in chewable tablets (given as 2 x 500 mg tablets) administered three times a day (for a total of 3000 mg/day) for 12 weeks |
| Placebo | Matching placebo chewable tablets administered 3 times a day for 12 weeks |

Measured Values

| | Lanthanum Carbonate | Placebo |
|---|---|---|
| Number of Participants Analyzed | 17 | 12 |
| Change From Baseline in Calcium-Phosphate Product Values at Week 12 (LOCF)<br>[units: mmol^2/L^2]<br>Least Squares Mean (Standard Error) | 0.0581 (0.0833) | 0.0710 (0.0993) |

Statistical Analysis 1 for Change From Baseline in Calcium-Phosphate Product Values at Week 12 (LOCF)

| | | |
|---|---|---|
| Statistical Analysis Overview | Comparison Groups | Lanthanum Carbonate, Placebo |
| | Comments | The null hypothesis was that there would be no difference between the 2 treatment groups in the mean change from baseline of Calcium-Phosphate Product at Week 12 (LOCF) in an analysis of covariance (ANCOVA) with treatment as a factor and the baseline Calcium-Phosphate Product as a covariate. |
| | Non-Inferiority or Equivalence Analysis? | No |
| | Comments | [Not specified] |

| | | |
|---|---|---|
| Statistical Test of Hypothesis | P-Value | 0.9220 |
| | Comments | The p-value was unadjusted and had no a priori significance level. |
| | Method | ANCOVA |
| | Comments | Not applicable |

| | | |
|---|---|---|
| Method of Estimation | Estimation Parameter | Mean Difference (Final Values) |
| | Estimated Value | -0.0129 |
| | Confidence Interval | (2-Sided) 95%<br>-0.2811 to 0.2553 |
| | Estimation Comments | [Not specified] |

## Reported Adverse Events

| | |
|---|---|
| Time Frame | [Not specified] |
| Additional Description | [Not specified] |

Reporting Groups

| | Description |
|---|---|
| Lanthanum Carbonate | 1000 mg in chewable tablets (given as 2 x 500 mg tablets) administered three times a day (for a total of 3000 mg/day) for 12 weeks |
| Placebo | Matching placebo chewable tablets administered 3 times a day for 12 weeks |

Serious Adverse Events

| | Lanthanum Carbonate | Placebo |
|---|---|---|
| | Affected/At Risk (%) | Affected/At Risk (%) |
| Total | 2/23 (8.7%) | 0/12 (0%) |
| Cardiac disorders | | |
| Cardiac failure | 1/23 (4.35%) | 0/12 (0%) |
| Myocardial ischemia | 1/23 (4.35%) | 0/12 (0%) |
| Gastrointestinal disorders | | |
| Pancreatitis acute | 1/23 (4.35%) | 0/12 (0%) |

Other Adverse Events
Frequency Threshold Above Which Other Adverse Events are Reported: 5%

| | Lanthanum Carbonate | Placebo |
|---|---|---|
| | Affected/At Risk (%) | Affected/At Risk (%) |
| Total | 2/23 (8.7%) | 0/12 (0%) |
| Gastrointestinal disorders | | |
| Constipation | 2/23 (8.7%) | 0/12 (0%) |

## Limitations and Caveats

[Not specified]

## More Information

Certain Agreements:

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

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

If a multicenter publication is not submitted within twelve (12) months after conclusion, abandonment or termination of the Study at all sites, or after Sponsor confirms there shall be no multicenter Study publication, the Institution and/or such Principal Investigator may publish the results from the Institution site individually.

Results Point of Contact:

Name/Official Title: Study Physician
Organization: Shire Development LLC
Phone: +1 866 842 5335

Email: