Trial record **1 of 1** for: NCT00147199

Previous Study | Return to List | Next Study

# Clinical Investigation Into Inhaled Treprostinil Sodium in Patients With Severe Pulmonary Arterial Hypertension (PAH) (TRIUMPH)



ClinicalTrials.gov Identifier: NCT00147199

Recruitment Status : Completed
First Posted : September 7, 2005
Results First Posted : August 12, 2013
Last Update Posted : August 12, 2013

**Sponsor:**
United Therapeutics

**Information provided by (Responsible Party):**
United Therapeutics

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

## Study Description

Go to

Brief Summary:

This is a double-blind placebo-controlled clinical investigation into the efficacy and tolerability of inhaled treprostinil in patients with severe pulmonary arterial hypertension. The primary outcome is the change in 6-minute walk distance from baseline to week 12.

| Condition or disease | Intervention/treatment | Phase |
|---|---|---|
| Pulmonary Hypertension | Drug: Inhaled treprostinil<br>Drug: Placebo inhalation solution | Phase 3 |

Detailed Description:

Patients who have been on a stable dose of 125 mg twice daily (bid) of bosentan or any stable dose of sildenafil for at least three months prior to study start were randomized to either treprostinil inhalation solution or matching placebo.

Administration of study medication was performed by inhalation with the OPTINEB™ ultrasonic nebulizer.

The proposed dosing regimen was four times daily—upon awakening, at midday, evening (dinner time) and bedtime.

After a patient has completed the twelve-week study period, they were given the option of enrolling into an open-label extension study.

## Study Design

Go to

| | |
|---|---|
| Study Type : | Interventional (Clinical Trial) |
| Actual Enrollment : | 235 participants |
| Allocation: | Randomized |
| Intervention Model: | Parallel Assignment |
| Masking: | Quadruple (Participant, Care Provider, Investigator, Outcomes Assessor) |
| Primary Purpose: | Treatment |
| Official Title: | TRIUMPH I: Double Blind Placebo Controlled Clinical Investigation Into the Efficacy and Tolerability of Inhaled Treprostinil Sodium in Patients With Severe Pulmonary Arterial Hypertension |
| Study Start Date : | June 2005 |
| Actual Primary Completion Date : | October 2007 |
| Actual Study Completion Date : | October 2007 |

**Resource links provided by the National Library of Medicine** NIH NLM

Genetics Home Reference related topics:
Pulmonary arterial hypertension

Drug Information available for: Treprostinil
Treprostinil sodium Treprostinil diolamine

Genetic and Rare Diseases Information Center resources: Pulmonary Arterial Hypertension

U.S. FDA Resources

## Arms and Interventions

Go to

| Arm | Intervention/treatment |
|---|---|
| Experimental: Inhaled treprostinil<br>0.9 mg/mL treprostinil for inhalation supplied in 2.9mL ampoules for use in ultra sonic nebulizer | Drug: Inhaled treprostinil<br>Doses are titrated to 9 breaths four times daily. Each breath produces an 18 mcg dose of inhaled treprostinil.<br>Other Name: Tyvaso |
| Placebo Comparator: Placebo<br>Placebo inhalation solution for use in ultrasonic nebulizer | Drug: Placebo inhalation solution<br>Doses are titrated to 9 breaths four times daily.<br>Other Name: Placebo |

## Outcome Measures

Go to

Primary Outcome Measures :

1. Peak 6-minute Walk Distance [ Time Frame: 12 weeks ]

   Change in peak 6-minute walk distance from baseline to Week 12. Peak 6MWD was defined as a 6-minute walk test (6MWT) within 10 to 60 minutes after study drug inhalation

Secondary Outcome Measures :

1. Clinical Worsening Events [ Time Frame: 12 weeks ]

   Clinical worsening was defined as the first incidence of clinical worsening from randomization to the first occurrence of death, transplantation, hospitalization for PAH, or initiation of additional approved PAH therapy.

2. Borg Dyspnea Score [ Time Frame: 12 weeks ]

   The Borg dyspnea score is a patient reported number between 0 (no perceived shortness of breath) and 10 (maximum perceived shortness of breath), obtained at the completion of each 6MWT.

3. New York Heart Association (NYHA) Functional Classification [ Time Frame: 12 weeks ]

   Change in NYHA functional class at Week 12. NYHA classifications:

   Class I - Patients with pulmonary hypertension but without resulting limitation of physical activity. Ordinary physical activity does not cause undue dyspnea or fatigue, chest pain or near syncope.

   Class II - Patients with pulmonary hypertension resulting in slight limitation of physical activity. They are comfortable at rest. Ordinary physical activity causes undue dyspnea or fatigue, chest pain or near syncope.

   Class III - Patients with pulmonary hypertension resulting in marked limitation of physical activity. They are comfortable at rest. Less than ordinary activity causes undue dyspnea or fatigue, chest pain or near syncope.

   Class IV - Patients with pulmonary hypertension in the inability to carry out any physical activity without symptoms. These patients manifest signs of right heart failure. Dyspnea and/or fatigue may even be present at rest. Discomfort is increased by any physical activity.

4. Trough 6MWD at Week 12 [ Time Frame: 12 Weeks ]

   Change in 6MWD from Baseline to trough 6MWD at Week 12. Trough was defined as a 6MWT conducted at least 4 hours following study drug inhalation.

5. Peak 6MWD at Week 6 [ Time Frame: 6 weeks ]

   Change in peak 6MWD between Baseline and Week 6.

6. Quality of Life (Minnesota Living With Heart Failure) [ Time Frame: 12 weeks ]

   Quality of life as measured by the Minnesota Living With Heart Failure (MLWHF) questionnaire was evaluated at baseline and at Week 12. The MLWHF questionnaire consists of 21 questions assessing how the patient's heart failure has prevented them from living the way they wanted during the defined time period. Each question was graded by the patient with a numeric value between 0 (No/none) and 5 (very much). These scores were then summed across the 21 questions for a Global Score. Global scores ranged from 0 to 105. These questions were further grouped into Physical (8 of the questions) and Emotional (5 of the questions) dimensions to further characterize the effect of heart failure on the patient's life. Physical scores ranged from 0 to 40, and emotional scores ranged from 0 to 25. For all 3 categories, the lower the score, the better the outcome. Values presented as change from Baseline.

7. Change in Signs and Symptoms of PAH [ Time Frame: 12 weeks ]

   Signs and symptoms of PAH (Loud P2 sound, Ascites, Right ventricular S3 sound, Dyspnea, Right ventricular S4 sound, Orthopnea, Right ventricular heave, Dizziness, Murmur of tricuspid insufficiency, Syncope, Murmur of pulmonic insufficiency, Chest pain, Hepatomegaly, Palpitations, Jugular venous distension at 45 degrees, Fatigue, Edema) were assessed at Baseline and Week 12. The status of each sign and symptom ("absent" or "present") was assessed at each visit. To assess overall change from baseline in signs and symptoms, a "1" was assigned for each sign and symptom that was "present" at the Week 12 but was "absent" at baseline, a "-1" was assigned for each sign and symptom that was "absent" at Week 12 but was "present" at baseline, and a "0" was assigned for no change. An overall change score at each post-baseline assessment was then calculated by summing these values for all signs and symptoms. The overall change score had the potential to range from -17 to 17.

8. N-terminal Pro-B-Type Natriuretic Peptide (NT Pro-BNP) [ Time Frame: 12 weeks ]

   Change in NT pro-BNP from Baseline to Week 12. Plasma samples were collected from patients at Baseline and Week 12 in order to measure any change over time in circulating plasma levels of this biomarker.

DOCKET ALARM

# Explore Litigation Insights

Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

## Real-Time Litigation Alerts

Keep your litigation team up-to-date with **real-time alerts** and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

## Advanced Docket Research

With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

## Analytics At Your Fingertips

Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

## API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

**LAW FIRMS**
Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

**FINANCIAL INSTITUTIONS**
Litigation and bankruptcy checks for companies and debtors.

**E-DISCOVERY AND LEGAL VENDORS**
Sync your system to PACER to automate legal marketing.