An Open-Label Extension Trial of UT-15C SR in Subjects with Pulmonary Arterial Hypertension

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To provide, or continue to provide, UT-15C SR for eligible subjects who participated in protocols TDE-PH-301 or TDE-PH-302 or TDE-PH-308 or additional UC-15C SR clinical protocols.To assess the long-term safety of UT-15C SR in these subjects through...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Pulmonary vascular disorders
Study type	Observational non invasive

Summary

ID

NL-OMON39044

Source
ToetsingOnline

Brief title
FREEDOM-EXT

Condition

- Pulmonary vascular disorders

Synonym
high bloodpressure in the small circulation; Pulmonal Arterial Hypertension

Research involving
Human

Sponsors and support

Primary sponsor: United Therapeutics Corporation
Source(s) of monetary or material Support: United Therapeutics Corporation

Intervention

Keyword: Extension, Pulmonary Arterial Hypertension, UT-15C

Outcome measures

Primary outcome

Efficacy Assessment: A 6-Minute Walk Test with Borg Dyspnea Score will be conducted at the study visit occurring 1 year after the subject first received UT-15C SR.

Safety Assessments: Adverse events and clinical laboratory parameters will be assessed throughout the study.

Secondary outcome

NA

Study description

Background summary

Combination treatment of PAH with therapies targeting different mechanisms of action has great promise in addressing the multiple pathophysiologic mechanisms that are implicated in PAH. These combinations may produce an additive effect or enhance and prolong the effect of other therapeutic agents.
Remodulin (treprostinil sodium) is an effective agent given by subcutaneous or intravenous delivery. UT-15C is a diethanolamine salt of treprostinil and is being investigated as a solid-dose oral compound. An oral product is easier to use.

Study objective

To provide, or continue to provide, UT-15C SR for eligible subjects who participated in protocols TDE-PH-301 or TDE-PH-302 or TDE-PH-308 or additional UC-15C SR clinical protocols.
To assess the long-term safety of UT-15C SR in these subjects through assessment of adverse events and laboratory parameters.

To assess the effect of continued therapy with UT-15C SR on exercise capacity after one year of treatment.

Study design

This is a multi-center, open-label study for eligible patients who participated in Protocol TDE-PH-301, TDE-PH-302 or TDE-PH-308.

Study burden and risks

For subjects on placebo at the end of the TDE-PH-301, TDE-PH-302 and TDE-PH-308 protocols, treatment will be initiated at 0,25 mg twice daily (every 12 hours +/- 1 hour) with dose escalation of an additional 0,25 mg or 0,5 mg twice daily every 3 days. The 0,125 mg strength, if available, may be used thoughout the study if a 0,25 mg dose increase is not tolerated and an intermediate dose is required.
For subjects on active therapy in TDE-PH-301, TDE-PH-302 or TDE-PH-308 the initial dose of the open-label study will be based upon their ending dose in the main pivotal studies.

Study visits will be timed to occur 3, 6, 12, 24, and 36 months after each subject*s first exposure to UT-15C SR and yearly visits beyond 36 months. Subjects receiving placebo in the previous study myst be contacted weekly by telephone during the first 12 weeks of the open label study. Monthly telephone calls must be conducted of all subjects actively participating in the TDE-PH-304. In addition to the study visits, all subjects must be seen in the clinic no less than once every six months for routine standard of care.

For subjects who were randomized to placebo in the previous study, the subject should remain close to the study site for approximately 3 to 6 hours for periodic observation and monitoring of possible AEs.

The most commonly observed side effects of UT-15C SR reported during previous studies included headache, nausea, diarrhea, facial flushing, jaw pain and pain in extremity.

The risks associated with the 6-Minute Walk Test may include the possibility of fatigue, fainting, muscle soreness, strain or injury.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

1. Subjects who remained on study drug and completed all assessments during the Treatment Phase of Study TDE-PH-301 or TDE-PH-302 or TDE-PH-308 are eligible for this study.
2. Subjects who permanently discontinued study drug during the Treatment Phase of the previous study (TDE-PH-301 or TDE-PH-302 or TDE-PH-308) due to clinical worsening, who completed all visits and received placebo.

Exclusion criteria

1. Subjects who permanently discontinued study drug during the previous study (TDE-PH-301 or TDE-PH-302 or TDE-PH-308) due to treatment related adverse events
2. Subjects who permanently discontinued study drug during the Treatment Phase of the previous study (TDE-PH-301 or TDE-PH-302 or TDE-PH-308) due to clinical worsening, who completed all visits and received active medication.
3. Subjects who permanently discontinued study drug during the Treatment Phase of the previous study (TDE-PH-301 or TDE-PH-302 or TDE-PH-308) due to clinical worsening and who did not undergo all visits.

Study design

Design

Study phase:	3
Study type:	Observational non invasive
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	18-12-2007
Enrollment:	30
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	not applicable
Generic name:	Treprostinil Diethanolamine

Ethics review

Approved WMO Date:	01-12-2006
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	12-03-2007
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	14-06-2007
Application type:	Amendment

Review commission:	METC Amsterdam UMC
Approved WMO Date:	19-06-2007
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	28-02-2008
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	11-09-2008
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	10-06-2009
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	26-04-2010
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	19-05-2010
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	28-05-2010
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	07-07-2010
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	14-10-2010
Application type:	Amendment

Review commission:	METC Amsterdam UMC
Approved WMO Date:	26-04-2011
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	19-07-2011
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	26-01-2012
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	28-09-2012
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	12-06-2013
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	11-07-2013
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	02-08-2013
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	04-10-2013
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	16-05-2014
Application type:	Amendment

Review commission:	METC Amsterdam UMC
Approved WMO Date:	12-06-2015
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	15-07-2015
Application type:	Amendment
Review commission:	METC Amsterdam UMC

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
EudraCT	EUCTR2006-000804-18-NL
Other	N/A
CCMO	NL15427.029.06