FUTURE 3 extension study.

Gepubliceerd: 17-12-2010 Laatst bijgewerkt: 18-08-2022

Evaluate the long-term safety, tolerability and efficacy of the pediatric formulation of bosentan two versus three times a day in children with pulmonary arterial hypertension (PAH).

Ethische beoordeling	Niet van toepassing
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON27501

Bron
Nationaal Trial Register

Verkorte titel
FUTURE 3 EXT

Aandoening

Pulmonary arterial hypertension in children

Ondersteuning

Primaire sponsor: Actelion Pharmaceuticals
Gewerbestrasse 16
CH-4123 Allschwil
Switzerland
Overige ondersteuning: Actelion Pharmaceuticals
Gewerbestrasse 16
CH-4123 Allschwil
Switzerland

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

No primary endpoint was defined in this study.

Toelichting onderzoek

Achtergrond van het onderzoek

This is a prospective, multicenter, multinational, open-label, double-arm exploratory Phase 3 extension study enrolling those patients who completed the FUTURE 3 core study (AC 052-373). It is designed to evaluate the long-term tolerability and safety of bosentan using the pediatric formulation in children with idiopathic or heritable PAH or PAH persisting after complete repair of a congenital heart defect.

Patients will receive the bosentan pediatric formulation. The bosentan dosage will be adjusted to the patient’s body weight during the study to achieve a maintenance dose of 2 mg/kg either b.i.d. or t.i.d.

The maximum number of participants corresponds to the number of patients treated in the FUTURE 3 core study (AC-052-373).

The study will be conducted at expert pediatric PAH centers in Europe, US, Latin America, Australia and Asia.

The study will consist of a treatment period and a post-treatment follow-up period of 60 days. Patients will receive the maintenance dose (2 mg/kg either b.i.d. or t.i.d.) of bosentan using the pediatric formulation for the entire duration of the study.

The treatment period in FUTURE 3 Study Extension will last for 12 months or until:

1. The investigator or the patient decides to discontinue the study treatment permanently;

2. The sponsor decides not to pursue the development of the pediatric formulation of bosentan.

Doel van het onderzoek

Evaluate the long-term safety, tolerability and efficacy of the pediatric formulation of bosentan two versus three times a day in children with pulmonary arterial hypertension (PAH).

Onderzoeksopzet

The study will consist of a treatment period and a post-treatment follow-up period of 60 days. Patients will receive the maintenance dose (2 mg/kg either b.i.d. or t.i.d.) of bosentan using the pediatric formulation for the entire duration of the study. The treatment period in FUTURE 3 Study Extension will last for 12 months or until:

1. The investigator or the patient decides to discontinue the study treatment permanently;

2. The sponsor decides not to pursue the development of the pediatric formulation of bosentan.

Onderzoeksproduct en/of interventie

Bosentan dispersible tablet (32 mg) in the dosage of 2 mg/kg b.i.d. or 2 mg/kg t.i.d.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Patients who completed the FUTURE 3 core study (AC-052-373) or prematurely

discontinued due to PAH progression, if bosentan was not permanently discontinued;

2. Patients who tolerated bosentan pediatric formulation and for whom bosentan is considered beneficial by the investigator at the end of FUTURE 3 core study (AC-052-373);

3. Signed informed consent by the parents or the legal representatives prior to any study-mandated procedure.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Known intolerance or hypersensitivity to bosentan or any of the excipients of the dispersible bosentan tablet;

2. Any clinically significant laboratory abnormality that precludes continuation of bosentan therapy;

3. Pregnancy;

4. AST and/or ALT values > 3 times the upper limit of normal range (ULN);

5. Moderate to severe hepatic impairment, i.e., Child-Pugh Class B or C;

6. Premature and permanent study drug discontinuation during the FUTURE 3 core study (AC-052-373);

7. Any major violation of the FUTURE 3 core study (AC 052 373) protocol.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Niet-gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Actieve controle groep

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-02-2011
Aantal proefpersonen:	64
Type:	Verwachte startdatum

Ethische beoordeling

Niet van toepassing

Soort:	Niet van toepassing

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL2538
NTR-old	NTR2656
Ander register	:
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten

N/A