Multi-center non-drug-interventional extension study to assess long-term safety and effects on growth in patients who received bosentan or placebo as adjunctive therapy to inhaled nitric oxide for persistent pulmonary hypertension of the newborn in FUTURE 4 (AC-052-391) (FUTURE 4 Extension)

First published: 07/11/2014

Last updated: 01/04/2024

Study Finalised

Administrative details

EU PAS number

EUPAS7910

Study ID

26193

DARWIN EU® study

No

Study countries

- [ ] Czechia
- [ ] Korea, Republic of
- [ ] Poland
- [ ] United Kingdom
- [ ] United States

Study description

The Extension of the research project FUTURE 4 to find out whether patients with persistent pulmonary hypertension of the newborn (PPHN) who received bosentan or placebo in addition to inhaled nitric oxide grow normally and to study whether they have late side effects.

Study status

Finalised

Research institutions and networks

Institutions

Actelion Pharmaceuticals

First published: 01/02/2024

Last updated: 01/02/2024

Institution

Great Ormond Street Hospital London, WC1N 3JH, United Kingdom, Norfolk and Norwich University Hospitals Norwich,UK, Všeobecná fakultní nemocnice Praha, Czech Republic, Klinika Neonatologii i Intensywnej Terapii Noworodka Warszawa, Poland, Ginekologiczno-Polozniczy Szpital Kliniczny Poznan, Poland, Samsung Medical Center Seoul, Republic of South Korea, Advocate Children's Hospital Oaklawn, USA, Ann and Robert H. Lurie Children's Hospital of Chicago Chicago, USA

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Pharmaceuticals Ltd ACTELION

Primary lead investigator

Study timelines

Date when funding contract was signed
Actual: 11/03/2013

Study start date
Actual: 14/12/2013

Date of final study report
Actual: 18/05/2015

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

ACTELION Pharmaceuticals Ltd.

Regulatory

Was the study required by a regulatory body?

Yes

Is the study required by a Risk Management Plan (RMP)?

Not applicable

Methodological aspects

Study topic:

Disease /health condition

Human medicinal product

Study type:

Clinical trial

Main study objective:

To assess long-term safety and effects on growth in patients who received bosentan or placebo in the FUTURE 4 (AC-052-391) study.

Study Design

Clinical trial regulatory scope

Pre-authorisation clinical trial

Clinical trial phase

Therapeutic confirmatory (Phase III)

Clinical trial randomisation

Non-randomised clinical trial

Study drug and medical condition

Medical condition to be studied

Pulmonary hypertension

Population studied

Short description of the study population

Patients with persistent pulmonary hypertension of the newborn (PPHN) who received bosentan or placebo in addition to inhaled nitric oxide grow normally.

Age groups

Term newborn infants (0 – 27 days)

Infants and toddlers (28 days – 23 months)

Special population of interest

Other

Special population of interest, other

Pulmonary hypertension of the newborn (PPHN) patients

Estimated number of subjects

21

Study design details

Data analysis plan

A Statistical Analysis Plan will be written and finalized before study closure.

Data management

Data sources

Data sources (types)

Other

Data sources (types), other

Prospective patient-based data collection, Retrospective data collection allowed

Use of a Common Data Model (CDM)

CDM mapping

No

Data quality specifications

Check conformance

Unknown

Check completeness

Unknown

Check stability

Unknown

Check logical consistency

Unknown

Data characterisation

Data characterisation conducted

Unknown