A retrospective-prospective observational study to assess Landiolol utilization patterns in patients with supraventricular tachycardia, for rapid control of ventricular rate in patients with atrial fibrillation or atrial flutter, for short-term control of the ventricular rate, or for non-compensatory sinus tachycardia (LANDI-UP)

First published: 03/09/2024

Last updated: 03/12/2024

Study Finalised

Administrative details

PURI

https://redirect.ema.europa.eu/resource/1000000297

EU PAS number

EUPAS1000000297

Study ID

1000000297

DARWIN EU® study

No

Study countries

- [ ] Austria
- [ ] Czechia
- [ ] Germany
- [ ] Greece
- [ ] Hungary
- [ ] Netherlands
- [ ] Poland
- [ ] Slovenia

Study description

A post-marketing, retrospective-prospective mulicenter, multinational non interventional study.

Primary Objective: To characterize Landiolol utilization patterns in patients treated according to the SmPC.

Primary Endpoint: Landiolol utilization patterns (total dose, infusion duration, starting/minimum/maximum dose, application route (central/peripheral line).

Secondary Objectives:

- to evaluate Landiolol effectiveness in a real-world setting
- to evaluate characteristics of patients treated with Landiolol intravenously in a real-world setting
- to evaluate the safety of patients treated with Landiolol intravenously in a real-world setting to facilitate life-cycle risk-benefit profiling
- to assess length of intensive/emergency care and hospital stay

- to survey the major cardiac outcome of patients treated with Landiolol up to 180 days

Secondary Endpoints:

Patient characteristics including medical history, reason for Landiolol use, left ventricular ejection fraction and use of concomitant medications

Efficacy data assessed within 4 hours after Landiolol discontinuation based on:

- percentage of patients with a heart rate control ≤ 110 beats per minutes (bpm) or 20% less than baseline
- percentage of patients with a heart rate control ≤ 90 bpm
- percentage of patients who recover the normal sinus rhythm
- proportion of patients requiring additional pharmacological or electrical cardioversion for rhythm control during hospital stay

Safety data up to 180 days after Landiolol initiation:

- adverse events (AEs) concerning number of patients and events, incidence rate, seriousness, intensity and relationship to study drug
- AEs requiring discontinuation of the treatment or treatment with specific therapy
- length of Intensive Care Unit (ICU)/Emergency Care Unit (ECU) and hospital stay
- major adverse cardiac events (MACE) by type: transient ischemic attack or ischemic stroke, myocardial infarction (STEMI and NSTEMI), cardiovascular death, all-cause mortality, etc.

Study status

Finalised

Research institutions and networks

Institutions

AOP Orphan Pharmaceuticals

First published: 01/02/2024

Last updated: 01/02/2024

Institution

Contact details

Study institution contact

Martin Unger

Study contact

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Primary lead investigator

Jolanta Siller-Matula

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 19/04/2020

Study start date

Planned: 09/07/2020

Actual: 09/07/2020

Date of final study report

Planned: 22/08/2024

Actual: 09/10/2024

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

AOP Orphan Pharmaceuticals GmbH

Regulatory

Was the study required by a regulatory body?

No

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

Not applicable

Methodological aspects

Study type

Study type list

Study topic:

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Drug utilisation

Study design:

A retrospective-prospective, multicenter, multinational observational study designed for patients suitable for Landiolol treatment in a hospital setting to assess drug utilization patterns. The study will not interfere with the usual patient care.

Main study objective:

Primary Study Objective:

- to characterize the drug utilization patterns in patients who were treated with Landiolol according to the SmPC

Secondary Study Objectives:

- to evaluate effectiveness of Landiolol treatment in a real-world setting
- to evaluate characteristics of patients treated with Landiolol intravenously in a real-world setting
- to evaluate the safety of patients treated with landiolol intravenously in a real-world setting to facilitate life-cycle risk-benefit profiling
- to assess length of intensive/ emergency care and hospital stay
- to survey the major cardiac outcome of patients treated with Landiolol up to 180 days

Study drug and medical condition

Name of medicine, other

Landiolol 300 mg powder for solution for infusion (Landiolol hydrochloride lyophilized powder 300 mg/50 ml)

Anatomical Therapeutic Chemical (ATC) code

(C07AB14) landiolol

landiolol

Medical condition to be studied

Supraventricular tachycardia

Atrial fibrillation

Atrial flutter

Sinus tachycardia

Population studied

Short description of the study population

The study population consists of adults (age 18 years old and over) patients receiving Landiolol for the treatment of supraventricular tachycardia, the rapid control of ventricular rate in atrial fibrillation or atrial flutter, other circumstances where the short-term control of the ventricular rate with a short acting agent is desirable, or non-compensatory sinus tachycardia.

Age groups

Adult and elderly population (≥18 years)

Adults (18 to < 65 years)

Adults (18 to < 46 years)

Adults (46 to < 65 years)

Elderly (≥ 65 years)

Adults (65 to < 75 years)

Adults (75 to < 85 years)

Adults (85 years and over)

Estimated number of subjects

450

Study design details

Setting

Having already been deemed suitable by their physicians for treatment with Landiolol, patients are treated intravenously in a peri-, postoperative, intensive care or emergency care setting, to assess drug utilization pattern, effectiveness, safety, patient characteristics and follow-up data on major adverse cardiac events up to 180 days.

The decision to initiate treatment with Landiolol will be the physician's responsibility and should be in accordance with the prescribing recommendation in the particular country. For each eligible patient, informed consent must be obtained (or a waiver is given, if the patient had died during Landiolol treatment, or were not capable of consenting) before entering data into the study electronic database. Patients could also be enrolled retrospectively, as long as treatment occurred after full regulatory approval and site activation.

Outcomes

The study protocol does not assign treatments, nor does it dictate what medical information should be entered into patient charts. Rather, each participating site provides and documents patient care and outcomes according to usual care, physician discretion and local practice standards. Thus, study variables may not be available for all patients at all time points, if data are not recorded

in the chart as per routine medical care.

Documents

Study report

LANDI-UP_Clinical Study Report_V1.0_English_17Sep2024_redacted.pdf(3.11 MB)

Data management

Data sources

Data sources (types)

Non-interventional study

Use of a Common Data Model (CDM)

CDM mapping

No

Data quality specifications

Check conformance

Yes

Check completeness

Yes

Check stability

Yes

Check logical consistency

Yes

Data characterisation

Data characterisation conducted

Yes