Safety registry for Eurartesim

First published: 03/07/2014

Last updated: 01/04/2024

Study Finalised

Administrative details

EU PAS number

EUPAS6942

Study ID

28484

DARWIN EU® study

No

Study countries

- Belgium
- France
- Germany
- Italy
- Netherlands
- Spain
- United Kingdom

Study description

A multi-centre safety registry for malaria patients treated with Eurartesim which aims to study the association between safety parameters (particularly QTc prolongation) and various factors including age, gender, ethnicity, lifestyle factors, food intake and co-morbidities/co-medications. Any patient with malaria who is treated with Eurartesim is eligible to participate. The registry aims to enrol 300 patients in 7 countries.

Study status

Finalised

Research institutions and networks

Institutions

ICON Commercialisation & Outcomes

Germany

Ireland

First published: 19/03/2010

Last updated: 05/07/2024

Institution | **Non-Pharmaceutical company** | **ENCePP partner**

Multiple centres: 19 centres are involved in the study

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Ron Behrens

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 01/11/2014

Actual: 01/11/2014

Study start date

Planned: 01/07/2012

Actual: 13/05/2013

Date of interim report, if expected

Planned: 03/07/2013

Actual: 03/07/2014

Date of final study report

Planned: 31/10/2017

Actual: 04/07/2018

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Sigma-Tau

Study protocol

3381_Eurartesim Safety Registry_Protocol_20120611_v6.0_Clean.pdf (781.51 KB)

Regulatory

Was the study required by a regulatory body?

Yes

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

EU RMP category 1 (imposed as condition of marketing authorisation)

Methodological aspects

Study type

Study type list

Study topic:

Disease /health condition

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Data collection methods:

Primary data collection

Main study objective:

The primary objective is to evaluate the association between safety parameters (in particular QTc prolongation) and the following - age, gender, ethnicity, lifestyle, food intake, co-medications and co-morbidities.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medicinal product name

EURARTESIM

Medical condition to be studied

Malaria

Population studied

Short description of the study population

Any patient with malaria who is treated with Eurartesim.

The following patients were included in the registry:

- Diagnosed with malaria (Plasmodium falciparum); diagnosis were clinically and parasitologically confirmed.
- Prescribed EurartesimTM treatment on the day on enrolment.
- Have been informed, provide consent to participate in this registry and sign the Informed Consent Form (ICF).

Age groups

- Infants and toddlers (28 days – 23 months)
- Children (2 to < 12 years)
- Adolescents (12 to < 18 years)
- Adults (18 to < 46 years)
- Adults (46 to < 65 years)
- Adults (65 to < 75 years)
- Adults (75 to < 85 years)
- Adults (85 years and over)

Special population of interest

Other

Special population of interest, other

Malaria patients

Estimated number of subjects

300

Study design details

Outcomes

The main focus of the statistical analysis is the assessment of the association between safety parameters (in particular QTc prolongation) and determinant factors. For QTc prolongation (Fredericia correction) and relevant laboratory parameters will be assessed via regression analysis. different transformations will be used to normalise the data if required. Assessment of AESI and QTc will be done. A descriptive analysis of the QTc data (absolute values, changes from baseline to day 3) using both Bazett (QTcB) and Fredericia (QTcF) corrections and laboratory values will be done. Descriptive statistics relating to the basic efficacy data will be presented. The incidence of all AEs and SAEs will be estimated and incidences of cardiac events, AESI and SAEs presented overall and by variable.

Data analysis plan

Continuous variables will be described by their mean, SD, median, quartile 1 and 3, extreme values and number of missing data. Categorical variables will be described by the total and % of each response method and the number of missing data. Continuous variables will be compared between subgroups using Students t-test or variance analysis. if the conditions for applying these tests are not met, Mann-Whitney, Wilcoxon or Kruskal-Wallis non-parametric tests will be used.Categorical variables will be compared between subgroups using the Chi-2 test if the theoretical total of each class studies is greater than 5. Otherwise Fisher's exact test will be used.The ordinal variables will be compared between subgroups using a Cochran-Mantal-Haenszel test.Hypothesis formulation will be bilateral, The tests will be performed for a first species alpha risk of 5%

Documents

Study results

EUPAS6942 Final results.pdf (28.66 KB)

Data management

ENCePP Seal

The use of the ENCePP Seal has been discontinued since February 2025. The ENCePP Seal fields are retained in the display mode for transparency but are no longer maintained.

Data sources

Data sources (types)

Other

Data sources (types), other

Prospective patient-based data collection

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