Effectiveness evaluation survey for Eurartesim

First published: 06/01/2015

Last updated: 28/02/2020

Study Finalised

Administrative details

EU PAS number

EUPAS8304

Study ID

33853

DARWIN EU® study

No

Study countries

France

Germany

Italy

Spain

United Kingdom

Study description

The European Medicines Agency (EMA) has requested Sigma-Tau to provide all physicians who are expected to prescribe or use Eurartesim with a healthcare professional educational pack. The EMA has requested Sigma-Tau to perform an Effectiveness survey in order to further assess physician understanding of this education material.This study will be conducted in 3 European countries by physicians who are expected to prescribe or use Eurartesim for the treatment ofmalaria. To study will ascertain the physician understanding of the education material provided about Eurartesim, in terms of drug indication, prescription modalities, administration modalities, high-risk patients, and potential side effects.The survey will be conducted respectively 12 months and 24 months after Eurartesim education material is delivered to the Physicians by the Sponsor. Physicians will be selected among a list of approximately 300 physicians per country, provided by the Sponsor.Approximately 60 Physicians per country are expected to participate.The following selection process will be conducted in each country respectively 12 months and 24 months after Physicians received education material:- A recruitment mail containing the study summary and a participation form will be sent to all Physicians.- Physicians will be asked to send back the completed participation form to Mapi. Characteristics of physicians, and if applicable, reason for non participation will be collected on the participation form.- Non-respondent Physicians will be contacted by telephone by Mapi, to know if they agree or not to participate in the survey.- The survey questionnaire will be administered by Mapi by phone to the Physicians selected for the survey and willing to participate.The results will be analysed according to the Statistical Analysis Plan written for the study.

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: 360 centres are involved in the study

Contact details

Study institution contact

Iannuccelli Maurizio Maurizio.Iannuccelli@sigma-tau.it

Study contact

Maurizio.Iannuccelli@sigma-tau.it

Primary lead investigator

Maurizio Iannunccelli

Primary lead investigator

Study timelines

Date when funding contract was signed
Planned: 01/09/2011

Actual: 01/09/2011

Study start date
Planned: 01/09/2013

Actual: 02/09/2013

Data analysis start date
Planned: 01/04/2014

Actual: 01/04/2014

Date of interim report, if expected
Planned: 30/06/2014

Actual: 01/07/2014

Date of final study report
Planned: 30/06/2015

Actual: 26/06/2015

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Sigma Tau

Study protocol

3366_Sigma Tau_Effectiveness Survey_Protocol_20130715_Final version_Signed.pdf (554.57 KB)

Regulatory

Was the study required by a regulatory body?

Yes

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

EU RMP category 3 (required)

Methodological aspects

Study type

Study type list

Study topic:

Other

Study topic, other:

Disease/Epidemiology study, Effectiveness evaluation of the education material provided about Eurartesim™

Study type:

Non-interventional study

Scope of the study:

Effectiveness study (incl. comparative)

Data collection methods:

Primary data collection

Main study objective:

To ascertain the physician understanding of the education material provided about Eurartesim, in terms of drug indication, prescription modalities, administration modalities, high-risk patients, and potential side effects.

Study Design

Non-interventional study design

Other

Non-interventional study design, other

Survey study (questionnaire)

Population studied

Short description of the study population

Physicians who were expected to prescribe or use Eurartesim for the treatment of malaria and who were delivered Eurartesim™ education material.

Inclusion criteria:

1. Physicians known to treat and follow-up patients with malaria
2. Physicians not participating in Pregnancy and Safety registries
3. Physicians who agree to participate in the survey

Age groups

- 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)

Estimated number of subjects

0

Study design details

Data analysis plan

Continuous variables will be described by their mean, standard deviation, median, quartiles 1 and 3, extreme values (minimum and maximum) and the number of missing data.Categorical variables will be described by the total and percentage of each response and the number of missing data. 95% confidence intervals will be computed on each individual percentage.Description of the study population:Characteristics of participating Physicians will be described.Response to the primary objective:- Knowledge of indication of Eurartesim will be described- Knowledge of prescription modalities of Eurartesim will be described- Knowledge of administration modalities of Eurartesim will be described- Knowledge of effects on cardiac repolarization will be described- Knowledge of high-risk patients will be described- Knowledge of potential side effects of Eurartesim will be described- Awareness of the pregnancy and safety registries and available information

Documents

Study results

EUPAS 8304 Final results.pdf (66 KB)

Data management

Data sources

Data sources (types)

Other

Data sources (types), other

Questionnaire completion by phone

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

No