Post Marketing Surveillance Study for Mircera

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Study | Finalised

Administrative details

PURI
https://redirect.ema.europa.eu/resource/20705

EU PAS number
EUPAS4683

Study ID
20705

DARWIN EU® study
No

Study countries
Korea, Republic of

Study description
This study (ML22560) is a post-marketing prospective surveillance study (conducted in Korea from 29 Aug 2008 to 28 Aug 2012) to meet local regulatory requirements.

Study status
Finalised

Research institution and networks

Institutions

F. Hoffmann-La Roche

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Institution

Multiple centres: 26 centres are involved in the study

Contact details

Study institution contact
Jenny Shin
Study contact

jenny.shin@roche.com
Primary lead investigator
Petersen Jenny
Primary lead investigator

Study timelines

Date when funding contract was signed
Actual:
02/01/2008

Study start date
Actual:
29/08/2008

Data analysis start date
Actual:
28/08/2012

Date of final study report
Actual:
28/11/2012

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

F. Hoffmann-La Roche

Regulatory

Was the study required by a regulatory body?
Yes

Is the study required by a Risk Management Plan (RMP)?
Non-EU RMP only

Other study registration identification numbers and links

ML22560

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
Effectiveness study (incl. comparative)

Data collection methods:
Primary data collection

Main study objective:
The main objectives are to evaluate the following items under routine practice:1) Serious adverse event(AE)/adverse drug reaction (ADR) 2) Unexpected ADR 3) Expected ADR 4) Non-serious AE 5) AE occurred by misuse, abuse and drug interaction 6) Any factors influencing safety and efficacy parameters (influencing lab. data, etc)

Study Design

Non-interventional study design
Other

Non-interventional study design, other
Prescription event monitoring

Study drug and medical condition

Name of medicine
Mircera

Medical condition to be studied
Anaemia

Population studied

Short description of the study population
Patients who were prescribed Mircera® by their physician according to the local Korean Mircera® label, for the treatment of anemia associated with chronic kidney disease who require Erythropoiesis-Stimulating Agents (ESA) therapy.

Age groups
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
Renal impaired

Estimated number of subjects
600

Study design details

Data analysis plan
According to the data, t-test or chi-square test was performed.Adverse events were tabulated in summary tables as followings:Summary table of incidence status of AEs/ADRs by System Organ ClassSummary table of drug - adverse events relationshipSummary table of Intensity of Adverse events/Adverse Drug ReactionsSummary table of Incidence rate Unexpected AEs/ADRs by System Organ Class

Data management

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