A Multi-Country Prospective Multi-Drug Resistant Tuberculosis Patient Registry to Monitor Bedaquiline Safety, Utilization, and Emergence of Resistance

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Study Finalised

Administrative details

PURI

https://redirect.ema.europa.eu/resource/40892

EU PAS number

EUPAS16023

Study ID

40892

DARWIN EU® study

No

Study countries

- [ ] Hong Kong
- [ ] Korea, Republic of
- [ ] Philippines
- [ ] South Africa
- [ ] Thailand

Study description

This study is a prospective, multi-country MDR-TB registry to further assess the benefits and risks of BDQ by evaluating BDQ safety, effectiveness, and emergence of resistance, BDQ drug utilization, and adherence to WHO guidance on the use of BDQ in MDR-TB treatment.

Study status

Finalised

Research institutions and networks

Institutions

Johnson & Johnson

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Institution

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Helen Pai

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 14/09/2015

Study start date

Actual: 03/05/2016

Date of final study report

Planned: 30/12/2020

Actual: 26/10/2020

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Janssen Research & Developmentt

Study protocol

TMC207TBC4002_Multi Country MDRTB Registry Protocol v2.0.pdf(182.7 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:

Human medicinal product

Disease /health condition

Study type:

Non-interventional study

Scope of the study:

Disease epidemiology

Drug utilisation

Data collection methods:

Combined primary data collection and secondary use of data

Main study objective:

To further assess the benefits and risks of BDQ by evaluating BDQ safety, effectiveness, and emergence of resistance, BDQ drug utilization, and adherence to WHO guidance on the use of BDQ in MDR-TB treatment.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Name of medicine

SIRTURO

Medical condition to be studied

Multiple-drug resistance

Pulmonary tuberculosis

Population studied

Short description of the study population

Inclusion Criteria

The study population will be drawn from the population of all patients treated

for MDR-TB in multiple countries. All patients newly diagnosed with MDR-TB as well as all patients newly treated with BDQ at participating sites will be eligible for inclusion in the registry. All patients meeting registry inclusion criteria will be eligible for inclusion in the registry provided they submit the necessary informed consent for participation.

Exclusion Criteria
No specific exclusion criteria will be applied in this study other than those scenarios that follow from the inclusion criteria.

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

Other

Special population of interest, other

Pulmonary tuberculosis patients

Estimated number of subjects

6000

Study design details

Outcomes

The registry is designed to observe several aspects of MDR-TB treatment such as drug utilization characteristics, treatment outcomes (clinical and microbiologic), and safety outcomes (adverse events and mortality).

Data analysis plan

Descriptive analyses will be used to describe baseline characteristics including demographics, country of origin, medical history, susceptibility of baseline MDR-TB isolates to BDQ and TB background regimen drugs, and use of medications at cohort entry. MDR-TB treatment will also be described including indication of use, dose, frequency, duration of use, usage with TB background regimen, and susceptibility of concomitant TB treatment regimens. Relative risk rates and 95% confidence intervals will be calculated and appropriate stratified analyses will be conducted for each adverse event, including death. Adjustments for imbalances between the treatment groups will be applied using accepted methods based on sample size availability and the observed overlap of key patient characteristics.

Documents

Study publications

Pai H, Ndjeka N, Mbuagbaw L, Kaniga K, et al. Bedaquiline safety, efficacy, uti...

Shim TS, Pai H, Mok J, et al. A prospective patient registry to monitor safety,...

Data management

Data sources

Data sources (types)

Disease registry

Drug registry

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

No