Multicenter prospective open-label non-interventional uncontrolled Post-Authorisation Safety Study (PASS) to evaluate the safety profile of Polyoxidonium in daily practice

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Study | Finalised

Administrative details

Contact details

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PURI
https://redirect.ema.europa.eu/resource/19533

EU PAS number
EUPAS12387

Study ID
19533

DARWIN EU® study
No

Study countries
Slovakia

Study description
This PASS aims to collect data on the safety of Polyoxidonium in patients, for whom Polyoxidonium is prescribed in routine practice in accordance with the terms of the marketing authorisation (MA). This is a local, multicenter, prospective, open-label, non-interventional, uncontrolled study. The decision to prescribe Polyoxidonium will be independent of the decision to enrol the subject into the study. Each subject will be observed for the duration of one cycle of Polyoxidonium treatment. In accordance with the SmPC, the treatment course consists of 5-10 injections depending on the disease. Thus, study duration for individual subject will take 7-23 days. There will be 5-10 study visits coinciding with routine visits to receive Polyoxidonium injections at the health care centre.Actual assessments undertaken at each visit will be determined by clinical practice. Subjects will not be administered any investigational medicinal products and/or medical procedures neither undergo any laboratory evaluations, diagnostic or monitoring procedures specifically for the purposes of this study.

Study status
Finalised

Research institution and networks

Institutions

MEDIGROUP s.r.o.

Multiple centres: 15 centers are involved in the study

Study timelines

Date when funding contract was signed
Planned:
28/07/2015
Actual:

28/07/2015

Data collection
Planned:
16/05/2016
Actual:
20/06/2016

Start date of data analysis
Planned:
02/01/2017
Actual:
10/02/2017

Date of final study report
Planned:
29/03/2017
Actual:
08/05/2017

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

NPO PETROVAXPHARM

Study protocol

Protocol_final version 1.1 2016 02 03_final clean.pdf(272.69 KB)

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:
Other

If ‘other’, further details on the scope of the study
This PASS aims to collect data on the safety of Polyoxidonium in patients, for whom Polyoxidonium is prescribed in routine practice in accordance with the terms of the marketing authorisation (MA).

Data collection methods:
Primary data collection

Main study objective:
The primary objective is: (a) to assess the frequency of adverse drug reactions(b) to estimate the proportion of subjects, who develop signs and symptoms of adverse renal effects associated with the use of Polyoxidonium.

Study Design

Non-interventional study design
Other

Non-interventional study design, other
This PASS is a local, multicentre, prospective, open-label, non-interventional, uncontrolled study.

Study drug and medical condition

Name of medicine, other
Polyoxidonium

Population studied

Short description of the study population
Adults aged 18 years or older receiveing Polyoxidonium prescription in accordance to the SmPC currently approved in Slovakia, i.e., for the treatment of any of the following

diseases or conditions accompanied by secondary immunodeficiency:
- chronic recurrent bacterial infection;
- chronic recurrent viral infection;
- acute bacterial infection;
- acute viral infection;
- allergic disease (pollinosis, bronchial asthma, atopic dermatitis)

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)

Estimated number of subjects
500

Study design details

Outcomes
The primary outcome is a proportion of subjects with adverse renal effects. Proportion of subjects who experienced any AE, ADR, SAE, serious ADRs.Number of subjects who discontinued the study,Global assessment of tolerability by investigators and by subjects,Global assessment of improvement by subjects and investigators,Mean duration of primary treatment of disease,Days with fever >38°C/days with symptoms,Total and differential WBC count in blood and urine.

Data analysis plan
This study focuses primarily on the safety profile of Polyoxidonium and no statistical hypothesis testing is intended. Statistical analysis will be merely descriptive in nature. Categorical data will be summarized in frequency tables. For continuous data, descriptive statistics will be calculated. For statistical comparison of categorical data, the chi-square test will be used. Parametric Student t-test or nonparametric Wilcoxon rank sum test will be used for comparison of continuous data between two independent samples. Parametric paired Student t-test or nonparametric Wilcoxon signed-rank test will be used for comparison of continuous data between two dependent samples. Proportions of two dependent samples will be compared using McNemar's test. Statistical tests will be interpreted at the 5% significance level (two-sided).Stratified analysis by indication will be performed to investigate safety profile and clinical benefit in different subjects subgroups.

Documents

Results tables
PASS report_final version 1.0 8 May 2017 SIGNED.pdf(3.77 MB)

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
No