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

First published: 10/02/2016

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Study Finalised

Administrative details

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 institutions and networks

Institutions

MEDIGROUP s.r.o.

Multiple centres: 15 centers are involved in the study

Contact details

Study institution contact

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Study contact

peter@bonusccs.sk

Primary lead investigator

Peter Pruzinec

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 28/07/2015

Actual: 28/07/2015

Study start date

Planned: 16/05/2016

Actual: 20/06/2016

Data analysis start date

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

Medicinal product name, 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

Study results

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

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

No