ASSESSMENT OF THE EFFICACY OF THE HEDUSSIN® MEDICINAL PRODUCT USE IN THE TREATMENT OF PRODUCTIVE (WET) COUGH

First published: 27/09/2017

Last updated: 31/03/2024

Study Finalised

Administrative details

PURI

https://redirect.ema.europa.eu/resource/22945

EU PAS number

EUPAS21094

Study ID

22945

DARWIN EU® study

No

Study countries

Poland

Study description

The staff that will take part in the study consists of paediatricians, general practitioners, internists, allergists, pulmonologists or doctors currently in the process of obtaining these specializations who lead the treatment of patients (in the form of outpatient healthcare) suffering from productive cough of various aetiologies in which, due to clinical indications, the HEDUSSIN® medicinal product has been introduced. Data on the efficacy of the treatment with the HEDUSSIN® medicinal product will be gathered in the Study Questionnaires (SQ) during two subsequent routine visits: first (1), where the Patient will be included in the Study, and second (2) approximately 7-10 days after the first one. The visits will be scheduled in accordance with the needs resulting from the Patient’s clinical state. The inclusion of the Patient into the group where the given treatment method is used should not result from the Study Protocol. It should be dependent solely on the current medical practice and remain in accordance with the current medical knowledge. The medical history collection period, conducted by 50 investigators, is scheduled for 3 months.

Study status

Finalised

Research institutions and networks

Institutions

Europharma

First published: 01/02/2024

Last updated: 01/02/2024

Institution

Contact details

Study institution contact

Zbigniew Doniec

Study contact

europharma@europharma.edu.pl

Primary lead investigator

Zbigniew Doniec

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 02/11/2016

Actual: 02/11/2016

Study start date

Planned: 01/12/2016

Actual: 01/12/2016

Data analysis start date

Planned: 31/03/2017

Actual: 31/03/2017

Date of interim report, if expected
Planned: 31/05/2017

Actual: 31/05/2017

Date of final study report
Planned: 15/10/2017

Actual: 27/09/2017

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Phytopharm Klęka S.A.

Study protocol

PAES HEDUSSIN PB ENG.pdf(249.38 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 topic:

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Disease epidemiology

Effectiveness study (incl. comparative)

Data collection methods:

Primary data collection

Main study objective:

Primary objective was efficacy of treatment with authorized medical product HEDUSSIN® in the therapy of productive cough in the course of respiratory tract infection in daily clinical practice (real life).

Study Design

Non-interventional study design

Other

Non-interventional study design, other

Post Authorization Efficiency Study (PAES)

Population studied

Short description of the study population

Patient of either sex, aged 2 to 12 with diagnosis of a productive (wet) cough of various aetiology who were recommented to use HEDUSSIN® were included during 1st visit

Age groups

Children (2 to < 12 years)

Special population of interest

Other

Special population of interest, other

Patients with productive (wet) cough

Estimated number of subjects

500

Study design details

Outcomes

Secondary objective was assessment of medical product HEDUSSIN® safety in the therapy of respiratory tract infection in daily clinical practice (real life).

Data analysis plan

The sample size of 500 Patients was based on the feasibility study. The analysis of the data obtained in the Study will be descriptive: the compiled data will consist of summarizing statistics such as quantities, average values, standard deviations, medians, minimal and maximal values of the observed frequencies/proportions. The effectiveness analysis will be conducted on the basis of the population of Patients who will partake in all of the visits described

in the Study Protocol.

Documents

Study results

REPORT Hedussin FIN.pdf(390.12 KB)

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