SEVIKAR HCT - treatment opportunity for patients with essential hypertension (SeviTarget)

First published: 20/11/2012

Last updated: 02/04/2024

Study | Finalised

Administrative details

EU PAS number

EUPAS3177

Study ID

9350

DARWIN EU® study

No

Study countries

Austria

Germany

Study description

Multi-national, open, prospective multi-center observational (non-interventional) study without any intervention by the sponsor regarding the selection of patients, diagnostic procedures or therapeutic decisions. / The observation period per patient is scheduled to a maximum of 24 ± 2 weeks. SEVIKAR HCT will be prescribed according to Summary of Product Characteristics. / Primary objective: To further investigate the safety profile of SEVIKAR HCT in daily practice and to collect data on so far unexpected adverse reactions as well as possible interactions with concomitant medications. / Secondary objectives are the efficacy within each of the Sevikar HCT dosages, patient compliance based on physician’s judgment, the disease burden in hypertensive patients, as well as the influence of chronobiological aspects on the tolerability and efficacy of the antihypertensive therapy.

Study status

Finalised

Research institutions and networks

Institutions

Institut für Pharmakologie und präventive Medizin

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Institution

Dr. Bramlage & Dr. Hankowitz Partnerschaft

Multiple centres: 999 centres are involved in the study

In total, 1100 centers are planned to be involved.

Contact details

Study institution contact

Peter Bramlage peter.bramlage@ippmed.de

Study contact

peter.bramlage@ippmed.de

Primary lead investigator

Christine Schober

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 15/02/2012

Study start date

Planned: 26/11/2012

Actual: 26/11/2012

Date of final study report

Planned: 31/03/2015

Actual: 09/12/2014

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Daiichi Sankyo European affiliates and Daiichi Sankyo Europe GmbH

Regulatory

Was the study required by a regulatory body?

No

Methodological aspects

Study type

Study type list

Study topic:

Human medicinal product

Disease /health condition

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Drug utilisation

Effectiveness study (incl. comparative)

Evaluation of patient-reported outcomes

Data collection methods:

Primary data collection

Main study objective:

Primary objective: To further investigate the safety profile of SEVIKAR HCT in daily practice and to collect data on so far unexpected adverse reactions as well as possible interactions with concomitant medications.

Study Design

Non-interventional study design

Other

Non-interventional study design, other

Non-Interventional Post-Authorisation Safety Study

Study drug and medical condition

Study drug International non-proprietary name (INN) or common name

OLMESARTAN MEDOXOMIL

AMLODIPINE BESILATE

HYDROCHLOROTHIAZIDE

Medical condition to be studied

Essential hypertension

Population studied

Short description of the study population

Consecutive male and female adult patients with diagnosis of essential hypertension who had started SEVIKAR HCT® therapy less than 2 weeks before patients’ Baseline visit (V1).

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

Essential hypertension patients

Estimated number of subjects

6.600

Study design details

Outcomes

Adverse Drug Reactions, Secondary objectives: Efficacy within each of the SEVIKAR HCT dose regimens in daily practice using various blood pressure related parameters and response criteria / Patient compliance / Patient reported outcome / Physicians' judgement of tolerability and efficacy

Data analysis plan

All variables collected in the CRF and all derived parameters will be used in statistical analysis. Binary, categorical and ordinal parameters will be summarized by means of absolute and percentage numbers within the various categories. Numerical data will be summarized by means of summary statistics (presented by visit, if useful). Pre-post differences will be calculated as post-baseline value minus baseline value. In addition, adequate figures (e.g. bar charts, box-whisker plots) may be presented to summarize the results for some parameters in a graphical way. Two-sided confidence intervals (CI) will be presented for important parameters, but should be interpreted in an exploratory descriptive way. No formal statistical tests will be performed within the statistical analysis. Depending on the variables of interest, additional selection criteria for patients (e.g. sub-group analyses) considered in specific analyses may be used, if considered useful during the statistical analysis.

Documents

Study results

20141209_SeviTarget_NIS Report Final v1 0.pdf (1.58 MB)

Study publications

Bramlage P, Fronk EM, Wolf WP, Smolnik R et al. Safety and effectiveness of a f...

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

Non-Interventional Post-Authorisation Safety Study

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