A long-term observational study to describe the use of PASCORBIN® 7.5 g in patients with vitamin C deficiency. (Long-term OBS PASCORB® 7.5 g)

First published: 06/05/2013

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Study Ongoing

Administrative details

EU PAS number

EUPAS3658

Study ID

27336

DARWIN EU® study

No

Study countries

☐ Germany

Study description

The aim of this long-term observational study is the documentation of the use of PASCORBIN® 7.5 g in patients with vitamin C deficiency.Regarding the vitamin C deficiency, we focus on the aquisition of data of the underlying diseases and the reduction of disease. Next to this, exact assessment of medical tolerance and details of treatment requirements ae further aims. Here we take into account acute and chronic underlying medical conditions are taken into account.The observational study began on 01 November 2012 and is scheduled for a period of 10 years continued (until 01 November 2022). The duration of the observational study for each patient is not fixed. There are 2 (for acute conditions) or 3 observation times (for chronic conditions) are provided.

Study status

Ongoing

Research institutions and networks

Institutions

Pascoe pharmazeutische Präparate

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Institution

pyhsicians and alternative practitioners Germany

Contact details

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Primary lead investigator

Bianka Krick

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 22/11/2012

Study start date

Planned: 01/11/2012

Actual: 05/11/2012

Data analysis start date

Planned: 01/11/2022

Date of final study report

Planned: 01/11/2023

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Pascoe pharmazeutische Präparate GmbH

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 type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Disease epidemiology

Effectiveness study (incl. comparative)

Main study objective:

The main aim was to measure the achievement of the treatment with Pascorbin® 7.5 g done by the documentation of the change in general and disease-specific symptoms.

Study Design

Non-interventional study design

Other

Non-interventional study design, other

Non-interventional observational study

Study drug and medical condition

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

ASCORBIC ACID

Medical condition to be studied

Vitamin C deficiency

Population studied

Age groups

Adolescents (12 to < 18 years)

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

5000

Study design details

Outcomes

global assessment of efficacy of treatment with PASCORBIN® 7.5 g, Global assessment of tolerability of treatment with PASCORBIN® 7.5 g, epidemiology of the underlying diseases, dosage scheme and therapy duration

Data analysis plan

For descriptive data:- qualitative and categorical data: absolute and relative frequencies,- quantative data: median, 25% - and 75% quantile, arithmetic mean, standard deviation, variance, minimum, maximum, and number of valid and missing data.Subgroups among 10 Pat. are not evaluated separately.The following statistical tests can be performed on explorative basis: Assessment of effectiveness of the theapy is compared with the corresponding assessment of previous med. using Fisher's Exact test. The change in individual symptoms between visit 1 and the last documented visit during therapy is checked using the Mantel-Haenszel test. For the corresponding change in the total symptom scores during the treatment of one-sample t-test is applied. Performing test statistical comparisons of said parameters between different subgroups is carried out in dependence of the real data. All tests are two-sided. Data-dependent, justified deviations (for example inadequate group size) may occur

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