Survey on experiences with phytopharmaceuticals via an online based questionnaire (PhytoVIS)

First published: 17/07/2014

Last updated: 01/04/2024

Study Finalised

Administrative details

PURI

https://redirect.ema.europa.eu/resource/28113

EU PAS number

EUPAS7082

Study ID

28113

DARWIN EU® study

No

Study countries

Germany

Study description

This study aims to collect data on application experiences of phytopharmaceuticals. The majority of phytopharmaceuticals in Germany are not covered by the statutory health insurance. Therefore GPs don't have the feasibility to prescribe herbal medicines nor to follow up the treatment. Furthermore the patients' compliance is hardly or not auditable. Data regarding reasons for applying pharmaceuticals, adverse effects or tolerance to herbal medicines are not systematically collected in Germany.PhytoVIS was initiated in order to gain information on the effect experience of patients taking phytompharmaceuticals. The study is not designed to take into account specific subgroups, but to collect data of all natural persons who have been taking herbal medicine during the previous eight weeks on the date of questioning. Amoung others the 'Clinical Global Impression Scale - Efficacy' (GGI-E) questionnaire will be used. Nota bene this study cannot deliver specific proofs on the effectiveness of different drugs. Rather PhytoVIS takes into account the overall effect experience during the therapeutic intervention. Thereby other factors and the course of disease play a role. Concerning adverse events no linkage to causal relationships is possible. Yet all adverse events will be documented and allow a more detailed evaluation. In addition to that data gained on children, pregnant women, and elderly people are valuable, since there are hardly any data available on these subgroups. A secondary endpoint of PhytoVIS is the collection of information on the way of purchase of the medicine as well as on way of recommendation, which will add to the knowledge on health services research.20 000 data sets will be collected via the online database 'PhytoVIS', that was successfully tested and validated in a pilot phase with 2000 data sets. Natural persons will be questioned at pharmacies.

Study status

Finalised

Research institution and networks

Institutions

Institute of Medical Statistics and Epidemiology (IMSIE Cologne)

Germany

First published: 17/07/2014

Last updated: 20/08/2024

Institution | Educational Institution | Not-for-profit

Contact details

Study institution contact

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Primary lead investigator

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Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 10/04/2014

Study start date
Planned: 07/07/2014

Actual: 08/07/2014

Data analysis start date
Planned: 01/02/2017

Actual: 01/02/2017

Date of final study report
Planned: 29/12/2017

Actual: 20/02/2018

Sources of funding

- Other

More details on funding

Kooperation Phytopharmaka

Study protocol

2014-0027-Protocol_SDPP_7082.pdf(112.43 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 topic:

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Drug utilisation

Other

If ‘other’, further details on the scope of the study

Health service research

Data collection methods:

Primary data collection

Main study objective:

Information about patients' experience on effectiveness and tolerance of phytopharmaceuticals.

Study Design

Non-interventional study design

Other

Non-interventional study design, other

Retrospective online survey

Population studied

Short description of the study population

The study population was not restricted in any way: any natural person had to be interviewed. The only inclusion criterion was that patients had to have taken an herbal medicinal product during the last eight weeks before the survey.

Age groups

Term newborn infants (0 – 27 days)

Infants and toddlers (28 days – 23 months)

Children (2 to < 12 years)

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)

Special population of interest

Hepatic impaired

Immunocompromised

Pregnant women

Renal impaired

Estimated number of subjects

20000

Study design details

Data analysis plan

For ascertainment of the patients' opinions and experiences on effectiveness and tolerance of phytopharmaca the validated scale of the questionnaire 'Clinical Global Impression Scale - Efficacy' (CGI-E) is utilised. The CGI-E consists

of a matrix with 16 fields that builds up the relation between adverse effects and therapeutic effects. The scores range from four (maximum) to 0,25 (minimum). An index of efficacy is calculated, where any values > 1.00 correspond to a predominant therapeutic effect, the value 1.00 means that the effects cancel each other out, any value < 1.00 reflects that adverse effects predominate.The secondary endpoint of the study, health service research on the phytopharmaceuticals' purchase and recommendation are inquired by questions about (1) the source of recommendations, e.g. pharmacist, doctor, family, friends, advertisement etc. and (2) the site of purchase, e.g. pharmacy, drug store, supermarket, organic food store.

Documents

Study results

PhytoVIS_Report_v1.0_final.pdf(782.47 KB)

Data management

ENCePP Seal

This study has been awarded the ENCePP seal

Conflicts of interest of investigators

2014-0027-DoI R Moesges_SDPP_7082.pdf(243.34 KB)

Composition of steering group and observers

Declaration_Steering_Committee_ENCEPP_SDPP_7082.pdf(429.82 KB)

Signed code of conduct

2014-0027-CoC_Declaration-SDPP_7082.pdf(543.88 KB)

Signed code of conduct checklist

2014-0027-CoC checklist-SDPP_7082.pdf(351.23 KB)

Signed checklist for study protocols

2014-0027-Checklist protocol-SDPP_7082 (2).pdf(437.7 KB)

Data sources

Data sources (types)

Disease registry

Drug dispensing/prescription data

Drug registry

Electronic healthcare records (EHR)

Other

Data sources (types), other

Prospective patient-based data collection, This study is a classical anonymously conducted survey based on an electronic CRF.

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