Retrospective online survey to investigate user experiences with herbal medicines (phytopharmaceuticals)/PhytoVIS

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Study Planned

Administrative details

EU PAS number

EUPAS1000000991

Study ID

1000000991

DARWIN EU® study

No

Study countries

Germany

Study description

With a few exceptions, phytopharmaceuticals have now become part of self-medication. This makes it difficult or even impossible to track their use by patients and document it.
So far, there's been little use of the chance to get info on how phytopharmaceuticals are used and tolerated at the point of recommendation. The info collected in Germany on phytopharmaceuticals is currently mostly limited to sales figures and the rather rare reports of adverse drug reactions. Against this background, the PhytoVIS project was launched in 2011 with the aim of advancing knowledge in the field of phyto-pharmaceuticals in healthcare. The goal was to develop an online tool that would enable doctors and pharmacists to retrospectively record their patients'/customers' experiences with all herbal preparations available in Germany.
In the previous productive phase of PhytoVIS (EUPAS7082, Study ID 28113), in which 20,000 patients/customers were surveyed on their use of herbal medicines, 24,000 data sets were evaluated.
The new productive phase of PhytoVIS is intended to supplement the results obtained in the data analyses of the previous productive phase.
The productive phase II is intended to gain further experience with the application of the PhytoVIS tool under real-life conditions. It covers all natural persons who have used phytopharmaceuticals in the last 8 weeks at the time of the survey. The purpose of PhytoVIS is not to collect data on the specific efficacy of phytopharmaceuticals – this is not possible within the framework of observational studies. Rather, the aim is to record how patients assess the effect within the overall therapeutic intervention. This is done in the knowledge that, in addition to the therapeutic interventions, many other influencing factors, such as the spontaneous course of the diseases being treated, play a role.
The focus should be shifted towards collecting data from children and adolescents, preferably through surveys conducted by paediatricians.

Study status

Planned

Research institutions and networks

Institutions

ClinCompetence Cologne

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Institution

Institute of Medical Statistics and Computational Biology (IMSB, University of Cologne)

Networks

Kooperation Phytopharmaka

Contact details

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Primary lead investigator

Ralph Mösges

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 01/08/2024

Actual: 15/08/2024

Study start date

Planned: 01/07/2025

Data analysis start date

Planned: 01/05/2027

Date of final study report

Planned: 01/07/2028

Sources of funding

More details on funding

Kooperation Phytopharmaka

Study protocol

PhytoVIS_observation_plan_V1-0.pdf (574 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:

Herbal medicinal product

Study type:

Non-interventional study

Scope of the study:

Drug utilisation

Effectiveness study (incl. comparative)

Evaluation of patient-reported outcomes

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

Health service research

Data collection methods:

Primary data collection

Study design:

The retrospective one-off survey regarding the use of phytopharmaceuticals within the last 8 weeks, is conducted at doctors' offices, pharmacies, etc. by students of medicine, pharmacy, or related fields which interview any patient. The students will survey about 100 patients (100 product data sets.

Main study objective:

The new productive phase of PhytoVIS is intended to supplement the results obtained in the data analyses of the previous productive phase.
The productive phase II is intended to gain further experience with the application of the PhytoVIS tool under real-life study conditions. It covers all natural persons who have used a phytopharmaceutical in the last eight weeks at the time of the survey. The purpose of PhytoVIS is not to collect data on the specific efficacy of phytopharmaceuticals – this is not possible within the framework of observational studies. Rather, the aim is to record how patients assess the effect within the overall therapeutic intervention. This is done in the knowledge that, in addition to the therapeutic interventions, many other influencing factors, such as the spontaneous course of the diseases being treated, play a role.
The focus should be shifted towards collecting data from children and adolescents, preferably through surveys conducted by paediatricians.
These special groups in particular show some significant results in the Clinical Global Impression Scale – Efficacy (CGI-E), which, however, need to be investigated further by increasing the number of cases..
With regard to adverse drug reactions, it is not possible to establish a causal link, e.g. with the use of certain products or with other therapeutic interventions. Furthermore, the statutory reporting system should not and cannot be duplicated. However, it will be ensured that adverse drug reactions that have led to a visit to a doctor can be reported via the questionnaire.
Due to the high number of data sets expected – a further 20,000 are targeted –

statistically sound, differentiated subgroup analyses are also possible and planned.

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 is not limited in this survey. Every natural person is to be surveyed, regardless of indication, product use, age, gender or ethnic origin. However, data on paediatric patients should be collected preferentially, e.g. by choosing an appropriate location for the survey, such as a paediatric doctor's office.

Age groups

- **In utero**
- **Paediatric Population (< 18 years)**
  - Neonate
    - Preterm newborn infants (0 – 27 days)
    - Term newborn infants (0 – 27 days)
  - Infants and toddlers (28 days – 23 months)

    - Children (2 to < 12 years)
    - Adolescents (12 to < 18 years)
- **Adult and elderly population (≥18 years)**
    - Adults (18 to < 65 years)
        - Adults (18 to < 46 years)
        - Adults (46 to < 65 years)
    - Elderly (≥ 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

Children, adolescents

Estimated number of subjects

20000

Study design details

Setting

The study will take place all over Germany. The following universities are involved: Goethe University (Frankfurt), Ludwig-Maximilians University (Munich), University Greifswald (Greifswald), University of Cologne (Cologne). Medical and pharmaceutical students of these universities will conduct the survey at any pharmacy (or any other point of sale for phytopharmaceuticals), doctor's practice, hospital, etc. The students have 4 weeks to collect at least

100 data sets.
The only inclusion criterion is that herbal medicinal products must have been used within the last eight weeks.
There are no exclusion criteria for this study.

Outcomes

Efficacy and tolerability of the products (user assessment)
The validated Clinical Global Impression Scale – Efficacy (CGI-E) is used to record the primary and secondary endpoints. The CGI-E scale is a 16-field matrix that shows the relationship between tolerability and therapeutic effect. Each field is assigned a score between 0.25 and 4.00. If the efficacy index is above 1.00, the therapeutic effect outweighs the adverse drug reactions in the respective dimension strength (1–2=marginal efficacy advantage vs. side effects; 3=moderate efficacy in the absence of side effects; 4=marked efficacy in the absence of side effects). With an index of 1.00, the effects cancel each other out. With a score of <1.00, the adverse drug effects outweigh the therapeutic effect.
Other outcomes:
Location of survey (Federal state, Place of administration)
Complaints/illness (Questionnaire on indication and symptoms, Type of treatment (acute, chronic, preventive), Question about perceived severity (based on the Numeric Pain Intensity Scale)
Information on the use of phytopharmaceuticals (Name of the product(s), Dosage, Time of application after onset of symptoms, Frequency, duration and dose of use, Time of onset of effect, Description of possible side effects for which a doctor was consulted, Source of recommendation for the product, Source of the product)
Accompanying factors/comorbidities (Other diseases in addition to the indication already mentioned, Use of other medicines)

Basic patient data (Age, Gender, Use during pregnancy or while breastfeeding)
General survey data (Comment on the case by the interviewer)

Data analysis plan

All questionnaires with the available data will be evaluated using IBM's SPSS statistical software or comparable programmes in the version available at the time of evaluation. In addition to the general target parameters, subgroup analyses (e.g. age groups, product groups, indication groups, etc.) will also be carried out as part of the evaluation.

Since the survey is not controlled and only takes place once, the data obtained is evaluated purely descriptively. Categorical data is presented using absolute and percentage frequencies. Numerical data is presented using the mean, median, standard deviation, 25/75 percentile, and minimum and maximum values.

After completion of the survey, the evaluation strategy is adapted to the given situation in an evaluation meeting. It is determined whether additional analyses appear useful and should be carried out in sub-collectives. If necessary, a statistical comparison between the subgroups can also be determined.

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)

Patient surveys

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