

Retrospektive Ärztebefragung zu Vorkommen und Ursachen von Stürzen bei älteren Patienten unter besonderer Betrachtung von Antihistaminika der ersten Generation als mögliche Sturzursache (Echo)

First published: 14/10/2019

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Study

Finalised

Administrative details

EU PAS number

EUPAS31817

Study ID

34160

DARWIN EU® study

No

Study countries

Study description

The Echo project is a retrospective survey of physicians on the incidence and causes of falls in older patients, with a special focus on first-generation antihistamines as a possible cause of falls. The background to this question is that in patients at ≥ 65 years of age an increased fall rate in connection with the intake of antihistamines of the first generation with sedative effect is discussed as a possible risk. No valid data are currently available to confirm or refute this risk. The primary objective of this study is to investigate a possible causal relationship between falls in patients at ≥ 65 years of age and the intake of antihistamines of the first generation with sedative effect. Secondary objectives are the investigation of a possible causal relationship of falls after the intake of antihistamines of the first generation with sedative effect for the subgroups < 65 years, 65-84 years and ≥ 85 years, the determination of the fall rate of patients ≥ 65 years as well as for the subgroups < 65 years, 65-84 years and ≥ 85 years, and the identification of causes for falls in patients ≥ 65 years. To answer this question, the design of a retrospective non-interventional post-authorisation safety study (according to § 63f German Drug Law) in the form of a cross-sectional study (medical chart review) is chosen. The survey will be conducted among at least 500 resident physicians, of which approx. 426 (~85%) are general practitioners/internists with no specialisation ($\hat{=}$ family doctors) and approx. 74 (~15%) are neurologists. Data collection is planned for October 2019 to December 2019. Data evaluation by means of descriptive statistics and study completion are planned for January 2020.

Study status

Finalised

Research institutions and networks

Institutions

STADA Arzneimittel

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Institution

Resident physicians (family doctors and neurologists) Germany

Contact details

Study institution contact

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Primary lead investigator

Friederike Klein

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 18/10/2019

Actual: 23/10/2019

Study start date

Planned: 29/10/2019

Actual: 29/10/2019

Data analysis start date

Planned: 17/12/2019

Actual: 12/12/2019

Date of final study report

Planned: 22/01/2020

Actual: 05/03/2020

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

STADA Arzneimittel AG

Regulatory

Was the study required by a regulatory body?

No

Is the study required by a Risk Management Plan (RMP)?

Not applicable

Other study registration identification numbers and links

STADA Study Code: PMS-36193-19-0204

Methodological aspects

Study type

Study type list

Study topic:

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Data collection methods:

Secondary use of data

Main study objective:

The primary objective of this study is to investigate a possible causal relationship between falls in patients at ≥ 65 years of age and the intake of antihistamines of the first generation with sedative effect.

Study Design

Non-interventional study design

Cross-sectional

Other

Non-interventional study design, other

Retrospective survey, Post-authorisation safety study

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code

(R06AA02) diphenhydramine

diphenhydramine

(R06AA09) doxylamine

doxylamine

Medical condition to be studied

Fall

Population studied

Short description of the study population

Resident physicians who were general practitioners/internists with no specialisation or neurologists.

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)
-

Estimated number of subjects

500

Study design details

Outcomes

Incidence and causes of falls in older patients in connection with the intake of antihistamines of the first generation with sedative effect.

Data analysis plan

Data evaluation by means of descriptive statistics.

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

Medical chart review

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