Apothekenbasierte, nicht-interventionelle Unbedenklichkeitsprüfung von Hoggar® Night Tabletten/Schmelztabletten unter Alltagsbedingungen (Projekt Alpha)

First published: 15/06/2020

Last updated: 14/03/2024

Study | Finalised

Administrative details

EU PAS number

EUPAS35589

Study ID

49911

DARWIN EU® study

No

Study countries

Germany

Study description

The Alpha project is a prospective, non-interventional post-authorization safety study in pharmacies investigating Hoggar® Night tablets/orodispersible tablets. The study is being conducted to collect data on the tolerability of Hoggar® Night under real-life conditions in a large, unselected group of patients. Of particular interest is the possible risk of an increased fall rate in patients ≥ 65 years of age, which is discussed in connection with the intake of antihistamines of the first generation with sedative effect. 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 Hoggar® Night. Secondary objectives are the investigation of a possible causal relationship of falls after the intake of Hoggar® Night 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 prospective, multicentric, non-interventional post-authorisation safety study (according to § 63f German Drug Law) interviewing purchasers of Hoggar® Night in pharmacies has been chosen. The study will be conducted with 2,000 patients in 200 to 400 pharmacies. Data collection is planned for quarter III/2020 to quarter II/2022. Data evaluation by means of descriptive statistics and study completion are planned for quarters II and III/2022.

Study status

Finalised

Research institutions and networks

Institutions

STADA Arzneimittel

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Institution

Multiple centres: 58 centres are involved in the study

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Andreas Iwanowitsch

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 29/01/2020

Actual: 29/01/2020

Study start date
Planned: 01/07/2020

Actual: 24/07/2020

Data analysis start date
Planned: 11/05/2022

Actual: 11/07/2022

Date of final study report
Planned: 15/11/2022

Actual: 10/11/2022

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-36193-19-0203

Methodological aspects

Study type

Study type list

Study topic:

Disease /health condition

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Safety study (incl. comparative)

Data collection methods:

Primary data collection

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 Hoggar® Night.

Study Design

Non-interventional study design

Cohort

Other

Non-interventional study design, other

Prospective, multicentric, post-authorisation safety study

Study drug and medical condition

Medical condition to be studied

Sleep disorder

Additional medical condition(s)

Fall

Population studied

Short description of the study population

The study focused on elderly patients aged 65 or above to examined the relationship between the risk of falls and the consumption of Hoggar® Night tablets/orodispersible tablets.

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

Frail population

Other

Special population of interest, other

Patients with sleep disorders

Estimated number of subjects

2.000

Study design details

Outcomes

Incidence of falls related to the Hoggar® Night intake.

Data analysis plan

Descriptive statistics: Subgroup analyses (gender, different age groups), absolute and relative frequencies for all data, mean, standard deviation, median, minimum and maximum for selected parameters. Primary/secondary objectives: Negative binomial models to investigate a possible causal relationship between the frequency of falls in patients taking Hoggar® Night and age, gender, dosage form, no. of comorbidities and concomitant medications. OR (incl. 95% CI) for each possible influencing variable. Fall rate of patients analysed descriptively, stratified by gender and age group. Fall rate defined as no. of patients with confirmed falls relative to no. of evaluable patients. Fall rates for all confirmed falls (regardless of the causal relationship with Hoggar® Night) and for the falls with a possible causal relationship with Hoggar® Night. Possible alternative fall causes with absolute and relative frequencies - for all patients as well as for patients ≥ 65 years.

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

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