Untersuchung der Sicherheit und Wirksamkeit von Alvalin® in einer prospektiven, nicht-interventionellen Sicherheitsstudie (PASS) - Evaluation of safety and efficacy of Alvalin in a prospective, non-interventional safety study (CTU 086H)

First published: 05/11/2013

Last updated: 04/02/2021

Study Ongoing

Administrative details

EU PAS number

EUPAS5084

Study ID

39374

DARWIN EU® study

No

Study countries

Germany

Study description

Untersuchung der Sicherheit von Alvalin® unter den Bedingungen des Praxisalltags. Weiterhin sollen Daten zur Dosierung, der Einnahmedauer, der Unterbrechung (inklusive der Gründe) und der Wirksamkeit unter Praxisbedingungen erhoben werden. Evaluation of safety of Alvalin for use in everyday practice. Furthermore data concerning dosage, duration of intake, interruption of treatment (with reasons) and efficacy for use in everyday practice should be collected.

Study status

Ongoing

Research institutions and networks

Institutions

Riemser Pharma

First published: 01/02/2024

Last updated: 01/02/2024

Institution

Contact details

Study institution contact

Dietmar Schroeder dietmar.schroeder@riemser.com

Study contact

dietmar.schroeder@riemser.com

Primary lead investigator

Christine Wettmarshausen

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 25/10/2013

Actual: 25/10/2013

Study start date

Planned: 13/01/2014

Actual: 31/01/2014

Data analysis start date

Planned: 01/02/2021

Actual: 01/02/2021

Date of final study report

Planned: 14/01/2022

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

RIEMSER Pharma 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

Drug utilisation

Effectiveness study (incl. comparative)

Main study objective:

Untersuchung der Sicherheit von Alvalin® unter den Bedingungen des Praxisalltags.Evaluation of safety of Alvalin for use in everyday practice.

Study drug and medical condition

Medicinal product name, other

Alvalin

Medical condition to be studied

Obesity

Population studied

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

1000

Study design details

Outcomes

Erfassung von Art und Häufigkeit von Beschwerden.Collecting of kind and frequency of adverse events. Erfassung von Daten zur Dosierung, der Einnahmedauer, der Unterbrechung (inklusive der Gründe) und der Wirksamkeit unter Praxisbedingungen.Collecting data concerning dosage, duration of intake, interruption of treatment (with reasons) and efficacy for use in everyday practice.

Data analysis plan

- in progress -

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