# 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

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**Institution**

# Contact details

**Study institution contact**

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**Primary lead investigator**

Christine Wettmarshausen

**Primary lead investigator**

## Study timelines

**Date when funding contract was signed**

Planned: 25/10/2013

Actual: 25/10/2013

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**Study start date**

Planned: 13/01/2014

Actual: 31/01/2014

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**Data analysis start date**

Planned: 01/02/2021

Actual: 01/02/2021

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**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

**Name of medicine, 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

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**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