Prospective, virtual, real-world data study in adults and adolescents ≥12 years with symptoms suggestive of acute rhinosinusitis (SinARv)

First published: 27/03/2025

Last updated: 31/10/2025

Study Finalised

Administrative details

EU PAS number

EUPAS1000000526

Study ID

1000000526

DARWIN EU® study

No

Study countries

Germany

Study description

The objective of the study is to collect real-world evidence and safety data for SinX in monotherapy and combination therapy, and to gain further insights into symptoms suggestive of acute rhinosinusitis (ARS), in adults and adolescents ≥12 years, using patient-reported outcome measures (PROMs).

Study status

Finalised

Research institutions and networks

Institutions

Bionorica SE

Germany

First published: 27/03/2025

Last updated: 27/03/2025

Institution | Pharmaceutical company

Contact details

Study institution contact

Christina Necker christina.necker@bionorica.de

Study contact

christina.necker@bionorica.de

Primary lead investigator

Claudia Bittner 0000-0002-7641-0351

Primary lead investigator

ORCID number:

0000-0002-7641-0351

Study timelines

Date when funding contract was signed

Planned: 06/08/2024

Actual: 06/08/2024

Study start date

Planned: 31/10/2024

Actual: 18/11/2024

Data analysis start date

Planned: 24/01/2025

Actual: 24/01/2025

Date of interim report, if expected

Planned: 31/01/2025

Actual: 31/01/2025

Date of final study report

Planned: 19/12/2025

Actual: 31/10/2025

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Bionorica SE

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:

Disease /health condition

Herbal medicinal product

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Drug utilisation

Effectiveness study (incl. comparative)

Evaluation of patient-reported outcomes

Safety study (incl. comparative)

Data collection methods:

Primary data collection

Study design:

Prospective RWD study -> online Patient survey (eDiary up to 14 days) using PROMs

Main study objective:

The objective of the study is to collect real-world evidence and safety data for SinX in monotherapy and combination therapy, and to gain further insights into symptoms suggestive of acute rhinosinusitis (ARS), in adults and adolescents ≥12 years, using patient-reported outcome measures (PROMs).

Study Design

Non-interventional study design

Other

Non-interventional study design, other

Prospective RWD study -> online Patient survey (e-Diary up to 14 days) using PROMs

Study drug and medical condition

Medicinal product name, other

Sinupret® extract, comprising a dry extract of gentian root (Gentiana lutea L.), primula flower (Primula veris L.), sorrel herb (Rumex crispus L.), elder flower (Sambucus nigra L.), and verbena herb (Verbena officinalis L.)

Anatomical Therapeutic Chemical (ATC) code

(R05X) OTHER COLD PREPARATIONS

OTHER COLD PREPARATIONS

Additional medical condition(s)

Acute Rhinosinusitis

Population studied

Short description of the study population

At least 5,000 patients are planned to be enrolled.

Patients eligible for study participation should meet the following inclusion criteria:

• Symptoms suggestive of ARS, which means sudden onset of 2 or more symptoms, one of which should be either nasal blockage / obstruction / congestion or nasal discharge (anterior/posterior nasal drip)

o ± facial pain/pressure

o ± reduction or loss of smell

• Age ≥12 years

Age groups

- 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)

Estimated number of subjects

5000

Study design details

Setting

The field phase of the study is expected to range from October 2024 until May 2025.

Each eligible patient will be followed-up daily for 14 days.

Please see information regarding study treatment below "Comparators".

Comparators

“Study treatment” is chosen by the participating patient (or prescribed by attending physician, if applicable) and may consist of SinX monotherapy or in combination with other cold medications, other cold medications only, or even no treatment.

All treatments should follow the instructions provided in the package leaflets of the respective drugs or the prescription made by the attending physician.

Outcomes

Patient-reported outcome measures (PROMs):
- MSSPAT and most bothersome MSS symptom
- Numerical rating scale (NRS) for bothersomeness of symptoms
- SNOT-20 GAV and 5 most important/bothersome items
- SNOT-16 (ARS) incl. 5 most important/bothersome items (in a subgroup of patients only)
- Overall assessment of effectiveness
- Overall assessment of tolerability
- Overall satisfaction with treatment

Data analysis plan

According to the non-interventional character of the study, the statistical analysis is descriptive and explorative.
No statistical hypotheses are postulated, and thus no inferential tests are planned.

Summary results

not yet available

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

Yes

Check completeness

Yes

Check stability

Unknown

Check logical consistency

No

Data characterisation

Data characterisation conducted

Yes