Post-authorisation observational safety study to examine the effectiveness of risk minimization measures in place in persons with an Anapen® prescription (PASS 21-08)

First published: 04/05/2026

Last updated: 13/05/2026

Study Planned

Administrative details

EU PAS number

EUPAS1000000972

Study ID

1000000972

DARWIN EU® study

No

Study countries

France

Study description

The primary objective is to assess the effectiveness of the risk minimization measures associated with Anapen® at the time of delivery by the pharmacist, in measuring the patients’ and relatives' knowledge on how to use Anapen® prior to its use. The injection will be simulated using Anapen® Trainer. Injection ability measurement will be standardized using a specific grid. The grid will list each action and distinguish minor errors that may affect the quality of the injection process without undermining its potential effectiveness from major errors that can lead to failure/inefficiency of the injection. Number of errors will be listed for each participant and the percentage of participants able to use the device correctly without major error will be calculated. Possibly, the percentages of participants able to use the device correctly will be assessed according to the participants’ level of education (i.e. knowledge of educational materials vs. lack of prior access).

The secondary objectives are to describe, the participant education with Anapen® provided by healthcare professionals the use of the disposable educational materials and the level of knowledge of the good practice for Anapen® using. Knowledge and understanding will be controlled using a questionnaire based on the main items of the prescriber's checklist and patient educational materials. The questionnaire will be carried out by the participant himself (patient or patient’s relative).

Study status

Planned

Research institutions and networks

Institutions

Bioprojet Pharma

France

First published: 07/05/2024

Last updated: 11/05/2026

Institution | Pharmaceutical company

Contact details

Study institution contact

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Study contact

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Primary lead investigator

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Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 13/03/2023

Study start date

Planned: 26/05/2026

Date of final study report

Planned: 31/12/2027

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Bioprojet Pharma

Study protocol

P21-08_C1715_PROTOCOL PASS_3.0_20250730-clean.pdf (3.59 MB)

Regulatory

Was the study required by a regulatory body?

Yes

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

EU RMP category 3 (required)

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:

Primary data collection

Study design:

This study is an observational, prospective, multicentric, national, study.
Primary data are collected via surveys.
Most relevant way to meet the primary objective is to assess the users' ability to perform a correct injection using a Trainer as they are expected to do in a situation of emergency.

Main study objective:

The primary objective is to assess the effectiveness of the risk minimization measures associated with Anapen® at the time of delivery by the pharmacist, in measuring the patients’ and relatives' knowledge on how to use Anapen® prior to its use.

The secondary objectives are to describe, the participant education with Anapen® provided by healthcare professionals the use of the disposable educational materials and the level of knowledge of the good practice for Anapen® using.

Study Design

Non-interventional study design

Other

Non-interventional study design, other

This study is an observational, prospective, multicentric, national, study.

Study drug and medical condition

Medicinal product name

ANAPEN

ANAPEN JUNIOR

Study drug International non-proprietary name (INN) or common name

EPINEPHRINE

Anatomical Therapeutic Chemical (ATC) code

(C01CA24) epinephrine

epinephrine

Medical condition to be studied

Anaphylaxis treatment

Population studied

Short description of the study population

The target study population will be all individuals complying with the following inclusion criteria:

- Adult person;
- Person who has been informed and who does not oppose to participate (“non-opposition” according to French provisions for observational studies);
- Person with Anapen® prescription (first or renewal) for himself/herself or for a relative;
- Person to whom the pharmacist has issued an Anapen® box in the current practice of pharmacy;
- Person participating to this study for the first time.

There are no exclusion criteria in the study.

Age groups

- **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)

Study design details

Setting

Participants: Adults coming to the pharmacy with a prescription for an Anapen® box, whether this prescription is for themselves or for a relative, and willing to participate could be enrolled after having been duly informed and given their oral consent (“non-opposition”).

Pharmacies: An estimation of 100 pharmacies spread over the national territory will participate as investigation sites. In each pharmacy, the pharmacist who will be designated as the site's principal investigator will be trained on the study requirements, in particular on filling out the CRF.
Start of the study: first participant included;
End of the study: last participant included;
Estimated total duration of the study:
- Inclusion period: one year;
- Maximum participation time of each participant: single visit of approximately one hour after obtaining the oral consent of the participant duly informed

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Outcomes

For primary objective: The injection will be simulated using Anapen® Trainer. Injection ability measurement will be standardized using a specific grid. The grid will list each action and distinguish minor errors that may affect the quality of the injection process without undermining its potential effectiveness from major errors that can lead to failure/inefficiency of the injection. Number of errors will be listed for each participant and the percentage of participants able to use the device correctly without major error will be calculated. Possibly, the percentages of participants able to use the device correctly will be assessed according to the participants' level of education (i.e. knowledge of educational materials vs. lack of prior access).

For secondary: Knowledge and understanding will be controlled using a questionnaire based on the main items of the prescriber's checklist and patient educational materials. The questionnaire will be carried out by the participant himself (patient or patient's relative).
will be assessed according to participants' level of education (i.e. knowledge of educational materials vs. lack of prior access).

Data analysis plan

Descriptive statistics will be employed to analyze the data. In brief, statistics for continuous variables will include mean, standard deviation, median, and range (minimum/maximum). Categorical variables will be presented as frequency counts and percentages. In addition, for all variables, a 95% confidence interval will be estimated.

A detailed statistical analysis plan describing the planned analysis and the approach for handling missing data will be developed prior to the data review

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Summary results

The summary of the final study report will be transmitted according to the local regulation within 1 year after the end of the study or within 3 months following the temporary interruption or early termination

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 source(s), other

The source of information for the study will be the data collected by the pharmacist dispensing Anapen® and participants' self-reported questionnaire.

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

Yes

Check logical consistency

Yes

Data characterisation

Data characterisation conducted

No