# Perioperative complication following anaesthesia in children with respiratory infection (RHUBARBE)

**First published:** 26/11/2016

**Last updated:** 30/03/2024

Study Finalised

## Administrative details

**EU PAS number**

EUPAS16436

**Study ID**

18531

**DARWIN EU® study**

No

**Study countries**

France

**Study description**

Description of complications (and presdictive factors of those complications) in children anaesthesized while presenting active or past respiratory infections

**Study status**

Finalised

# Research institutions and networks

## Institutions

### Hôpital Robert Debré

**First published:** 01/02/2024

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**Institution**

Rennes Rennes (France), Clermont-Ferrand Clermont-Ferrand (Ferance), Lilles Lilles (France), Marseille 1 (Timone) Marseille (France), Marseille 2 (Nord) Marseille (France), Nantes Nantes (France), Nice Nice (France), Nimes Nimes (France), Nouméa Nouméa (France), Reims Reims (France)

## Contact details

**Study institution contact**

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**Study contact**

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**Primary lead investigator**

Dahmani Souhayl

**Primary lead investigator**

## Study timelines

**Date when funding contract was signed**

Planned: 26/11/2016

Actual: 26/11/2016

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**Study start date**

Planned: 02/01/2017

Actual: 24/11/2016

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**Data analysis start date**

Planned: 01/07/2017

Actual: 24/11/2016

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**Date of interim report, if expected**

Planned: 01/12/2017

Actual: 24/11/2016

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**Date of final study report**

Planned: 31/03/2018

Actual: 26/11/2016

## Sources of funding

- Other

## More details on funding

Government body

## Study protocol

Etude Rhubarbe.pdf (391.07 KB)

## 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

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**Study type:**

Non-interventional study

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**Scope of the study:**

Assessment of risk minimisation measure implementation or effectiveness

Disease epidemiology

**Data collection methods:**

Combined primary data collection and secondary use of data

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**Main study objective:**

Determining major respiratory complications during anaesthesia in children with respiratory tract infection

## Study Design

**Non-interventional study design**

Cohort

## Study drug and medical condition

**Medical condition to be studied**

Respiratory symptom

## Population studied

**Short description of the study population**

Children aged ≥ 1 month anaesthesized while presenting active or past respiratory infections.

Children ≥ 1 month of age with ASA I to IV, and any surgery were included.

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**Age groups**

- Infants and toddlers (28 days – 23 months)
- Children (2 to < 12 years)
- Adolescents (12 to < 18 years)

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**Special population of interest**

Other

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**Special population of interest, other**

Respiratory infection patients

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**Estimated number of subjects**

1.000

# Study design details

**Outcomes**

The incidence and prevalence of major respiratory and general complications during anaesthesia in children with respiratory tract infection, -The risk foactor of major respiratory and general complications during anaesthesia in children with respiratory tract infection- Factors leading to delayed or not naesthesia during anaesthesia in children with respiratory trat infection

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**Data analysis plan**

Descriptive statistics (mean, sd, median, ranges, N, %)Multivariate analysis : logistic regression and/or Tree analysis

# 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)**

Electronic healthcare records (EHR)

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**

Unknown