Prospective intervention study to determine the anesthesia workplace exposure to sevoflurane when using activated carbon filters vs. anesthesia gas scavenging systems. CONTRAGASS

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Study Ongoing

Administrative details

EU PAS number

EUPAS1000000807

Study ID

1000000807

DARWIN EU® study

No

Study countries

Germany

Study description

Small amounts of anesthetic gas inevitably escape during anesthesia due to device-specific leaks and the gas's high volatility. The plan is to compare workplace exposure to anesthetic gases in the operating room using an anesthetic gas scavenging system versus anesthetic gas absorber.
For this purpose, an automated measuring device will be operated in an operating room. The two methods will be connected prospectively and randomly to the standard ventilator (PRIMUS, Dräger).
The goal is to compare the minimum residual gas concentration of sevoflurane in the room air per minute of anesthesia as an indicator of workplace exposure.

Study status

Ongoing

Research institutions and networks

Institutions

Hannover Medical School (MHH)

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Institution | Educational Institution | Hospital/Clinic/Other health care facility

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Sebastian Heiderich

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 27/10/2025

Actual: 27/10/2025

Study start date

Planned: 02/11/2025

Actual: 02/11/2025

Data analysis start date

Planned: 21/12/2025

Date of final study report

Planned: 02/05/2026

Sources of funding

- No external funding

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:

Medical device

Study type:

Not applicable

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Data collection methods:

No individual level data collected for the purpose of the study

Study design:

We will measure the concentration of sevoflurane 20 common workdays in de Operationroom. We will randomly use for 10 days the common anesthetic gas scavenging system and 10 days the anesthetic gas absorbers CONTRAFLURAN.

Main study objective:

The concentration of sevoflurane in ppm in the operation room during anesthesia.

Study Design

Clinical trial regulatory scope

Post-authorisation interventional clinical trial

Clinical trial randomisation

Randomised clinical trial

Population studied

Short description of the study population

People over the Age of 18

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)

Special population of interest

Other

Special population of interest, other

Patients from the departement of ophtamology

Estimated number of subjects

20

Study design details

Setting

We will measure the concentration of sevoflurane 20 common workdays in de Operationroom. We will randomly use for 10 days the common anesthetic gas scavenging system and 10 days the anesthetic gas absorbers CONTRAFLURAN.

Interventions

The use of the anesthetic gas absorbers CONTRAFLURAN.

Comparators

A common anesthetic gas scavenging system.

Outcomes

1. The workplace exposure to sevoflurane is < 2 ppm on average over 8 hours in the test and control groups.
2. Workplace exposure to sevoflurane does not differ between the test and control groups.

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.

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