Accuracy of Pleth Variability Index (PVI) in Predicting Response to Intravenous Fluid load During Scoliosis Surgery in Children.

First published: 18/12/2012

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Study Planned

Administrative details

EU PAS number

EUPAS3238

Study ID

3239

DARWIN EU® study

No

Study countries

France

Study description

This study is an observational non-intervention study. This work aim to study the accuracy of Plethysmographic Variability Index (PVI) during scoliosis surgery in children.It consists on an observational study on PVI values before fluid challenges (using 20 ml/Kg of a normal saline solution) performed during this surgical procedure. The goal standard for a response to a fluid challenge is an increase of the indexed stroke volume (determined using an oesophageal doppler) by more than 15 %.Number of patients to be included in this study is 50.

Study status

Planned

Research institutions and networks

Institutions

Hôpital Robert Debré

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Institution

Contact details

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Primary lead investigator

DAHMANI Souhayl

Primary lead investigator

Study timelines

Date when funding contract was signed
Planned: 11/12/2012

Study start date
Planned: 01/01/2013

Data analysis start date
Planned: 02/12/2013

Date of final study report
Planned: 03/03/2014

Sources of funding

- Other

More details on funding

Department Funding

Regulatory

Was the study required by a regulatory body?

No

Methodological aspects

Study type

Study type list

Study type:

Non-interventional study

Scope of the study:

Effectiveness study (incl. comparative)

Other

If ‘other’, further details on the scope of the study

Accuracy of a routinely used device

Main study objective:

Study the accuracy of Plethysmographic Variability Index to predict a response to fluid challenge

Study Design

Non-interventional study design

Cohort

Population studied

Age groups

- Children (2 to < 12 years)
- Adolescents (12 to < 18 years)

Estimated number of subjects

50

Study design details

Outcomes

Finding values of Plethysmographic Variability Index predicting a response to fluid challenge

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Data analysis plan

ROC analysis with determination of the gray zone

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)

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