Fluid Challenge in Intensive Care: a worldwide global inception cohort study. The Fenice II study.

Research question?

What is the modality of fluid administration in ICU patients worldwide and what is the impact of fluid administration on clinical outcomes?

Background

Fluids are considered the primary treatment for critically ill patients admitted to the intensive care unit (ICU), aiming to replace losses and or to enhance venous return, stroke volume, and consequently, cardiac output and tissue oxygen delivery. The modalities, volumes, and targets employed to titrate fluid therapy vary significantly in current clinical practice, as shown by the original FENICE study 10 years ago. FENICE studied how fluid challenges are given at the bedside. Very little is known about how this practice has changed since, how fluid administration (maintenance) is performed in general, and how the modality may impact outcomes. FENICE II is designed to explore these issues.

Objectives

To provide a comprehensive global description of fluid administration modalities during the initial days of ICU admission and to explore any association between fluid administration characteristics and clinical outcomes.

To describe the fluid challenge administration modality and appraise the use of variables and functional haemodynamic tests to guide bolus infusion.

Study design

Prospective multicentre worldwide study.

Population

Inclusion criteria:

- All consecutive adult patients (≥ 18 years) admitted to ICU and expected to stay at least 48h.

Exclusion criteria:

- Refusal of consent.
- Planned admission after surgery for overnight ICU stay.
- Moribund patients (i.e. expected survival < 24h).

Enrollment and study periods: We have two data collection periods to choose from:

The phase of centers enrolment will be conducted over a time window of 12 months starting from 1st January 2024.

The phase of patients' enrolment will be conducted over a two-weeks period (14 days), chosen within a time window of 6 months starting from 1st January 2025.

The study period for data collection regarding the modality of fluid administration will consider the first 5 days from ICU admission (ICU days 1-5).

Aims

Primary aim: The primary aim is to describe the modality of fluid administration during the first 5 days of ICU stay considering 1) the overall fluid balance; 2) the characteristics of the fluids given; 3) the modality of fluid administration.

Secondary aims:

- To explore any association between fluid administration characteristics and clinical outcomes (see further)
- To evaluate factors potentially associated with the respective proportion of the different modalities of fluid administration
- To characterize FC administration modality in a large cohort of ICU patients.

Clinical outcomes:

- In-hospital, intensive care unit, and 30-day mortality.
- Major organ dysfunction: lungs, heart and circulatory system, kidneys.
- Variation in SOFA score within 7 days from admission.

Functional outcomes:

- Volume of resuscitation fluids within 5 days from admission, type of fluid, and modality of administration.

Net daily fluid balance within 5 days.

Data Collection

Data All data generated in participating centres will be systematically recorded using the study management software RedCap (Research Electronic Data Capture) and uploaded through a secure connection to an encrypted database in Humanitas Research Hospital (Milan, Italy) servers.

Study Duration

The enrollment phase of the study will span a two-week period during the 2024. This time frame follows a preliminary period dedicated to trial dissemination and the recruitment of participating centers. Data collection regarding the modality of fluid administration will be focused on the first 5 days of ICU admission.

Safety

The study will be based on descriptive variables from routine available data and will not affect treatment or handling of the patients included (observational study).

Authorship

Centres' coordinators and site investigators will be acknowledged either on the front page or under the group authorship ("FENICE II Study Group") with the specific order determined by factors such as the number of included patients per study site, overall commitments, and centres' recruitment. For multiple coordinators and/or investigators, authorship criteria will be evaluated at the end of the by the Steering Committee.

Do I need IRB approval?

Ethics committee and appropriate **local** regulatory approvals must be obtained by each investigator prior to enrolling patients. Each centre is responsible for ethical approval and approval and patient consent.

How is the data that is collected managed?

All data is anonymised and cannot be linked to individual subjects. The data will be stored securely and all procedures regarding data management will comply with General Data Protection Regulation (GDPR) 2016/679/EU. The eCRF platform is licensed from RedCap and administered by RCCS Humanitas Research Hospital.

Who owns and can access the collected data?

According to the ICH Guidelines on Good Clinical Practice the sponsor of a study (the Institution, should the investigator or study coordinator act as sponsor in the performance of her/his institutional duties under the employment or collaboration agreement with Humanitas) is the owner of the data resulting therefrom. All centres and investigators participating in the study should be made aware of such circumstance and invited not to disseminate information or data without the Institution's prior express consent.

Is there any financial compensation?

There is no financial compensation for participation. Participation in the study is completely voluntary.

How do I participate?

Please contact your national coordinator (see list hereunder).

Centers will be supported by national coordinators and SC members regarding EC submission process, according to local regulations

National Coordinators

You can contact your national coordinator if you need help for your ethical approval: (see list hereunder).

Principal Investigators

Principal Investigator: Pr Maurizio Cecconi MD, PhD
Co-Principal investigator: Dr Antonio Messina, MD PhD

Steering Committee

Elie Azoulay, Maurizio Cecconi, Michelle Chew, Michael Darmon, Daniel De Backer, Lennie Derde, Jan De Waele, Katia Donadello, Ignacio Martin-Loeches, Antonio Messina, Xavier Monnet, Marlies Ostermann, Jean-Louis Teboul.

Any further Questions?

Please read Frequently Asked Questions (FAQs) document (soon available).

You can contact Antonio Messina at mess81rc@gmail.com
ESICM office: research@esicm.org

Registration of Fenice II

PRS number: NCT06394947

Documents

Study Protocol Fenice II

CRF Form (*draft for IRB approval*)

DUA in French

DUA in Italian

DUA in Spanish

Ethical Approval for the Principal Investigators (IRCCS Humanitas Research Hospital, Rozzano(MI), Italy)

Informed Consent Waiver Statement

Consent Form Template (Patient)

Consent Form Template (Legal representative)

NC meeting – 2 May 2024

List of National Coordinators (last update 03 June 2024)

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