Information overview of the VIP2 study (POETIC2 in UK)

Very old Intensive Care Patient-study 2: Development and validation of a prognostic score

An ESICM supported study conducted from the HSRO & NAHP section in ESICM

Background and scope:

This study will seek to develop a prognostic score for specifically very old, critically ill patients (defined as patients ≥ 80 years). This is a large, prospective, multinational, multicentre study.

We will gather age-specific information about the elderly patient: frailty, cognitive function, activity of daily life and co-morbidity, in addition to organ failure score. Outcomes will be registered as outcome at 30 days (alive or dead) and 6 months in a sub-study. Also an inter-rater variability will be registered in a sub-study within the main study.

Recruitment of patients

The goal is to recruit 20 consecutive ICU patients ≥ 80 years, or continue for a 6 months period. Based on a previous multicentre study (the VIP1) we hope to recruit 200-250 ICUs and 4000-5000 patients.

Ethics

We will not register any patient specific identifying information. We will only register gender and age (in rounded years). Each participating country of course must comply to their national rules for such a study. This means that appropriate ethical approval should be sought by national (or local) ethical committees for the need for patient informed consent and sending data to an external server. In some countries this will be (partially) done by the national coordinators (see list).

How to record data?

We use the same dedicated server as in the VIP1-study, which is located at the Department of Clinical Medicine, Aarhus University, Aarhus, Denmark. We have created a simple e-CRF for this study. It will be easy to enter both ICU background data and patient data. All in all, there are 19 different variables to register, some simple (like age) and some more compound like SOFA score. The ICU background data must be collected before start of patient recruitment. The links to e-CRF and other documents related to the VIP2 study can be found on the website (www.vip2study.com).

Data security and storage

Data security in the VIP2 study follows industry standards. The data entry forms and database run on a secured server and are composed of a MySQL database and PHP web-application. Data is secured with Secure Socket Layer (SSL) encryption when transported into the database and data is stored on servers located on the campus of Aarhus University, Aarhus C, Denmark. The servers are maintained and managed in a professional server environment in co-operation between the IT Department and the Department of Clinical Medicine. The server rooms have physical access control and logging of personnel access. Other security measures include hardware and software firewalls. For technical inquiries please contact the data-manager: Jesper Fjølner, MD. email: contact@vip2study.com.

Study start

Our goal is to open for ICU recruitment from May 2018, and to start inclusion for 6 months. In the meantime, it is important to seek the necessary ethical approval (local/national regulations) for collecting data.

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Data to be registered:

- Age & Gender
- Date of admission
- Reason for admission (only acute admission): separate list
- At admission recording of:
    - Clinical Frailty Scale
    - Activity of Daily Life (Katz ADL)
    - Cognitive function: IQCODE
    - Co-morbidity (CPS score)
    - SOFA score at admission (as each individual organ failure score (6))
    - Inter-rater variability of CFS (a sub-study)
- During admission recording of
    - ICU LOS as hours
    - Hospital LOS (days)
    - Intubation and MV (hours)
    - Vasoactive drugs (hours)
    - Non-invasive ventilation
    - RRT
    - Tracheostomy
- Vital status at
    - ICU discharge (all)
    - 30 days (all)
    - 6 months (in a sub-study cohort)