Centre for Research in Intensive Care

The CLASSIC trial is approved by the national ethic committees and health authorities

Contact information:

Tine S. Meyhoff, coordinating investigator
classic@cric.nu
Telefon: +45 3545 0606

Anders Perner, sponsor
anders.perner@regionh.dk
Telefon: +45 3545 8333

Classic

Conservative vs Liberal Approach to Fluid Therapy of Septic Shock in Intensive Care (CLASSIC) trial

Information for doctors & nursing staff

Your department participates in the
CLASSIC TRIAL

The CLASSIC trial assesses benefits and harms of IV fluid restriction vs standard of care in adult ICU patients with septic shock

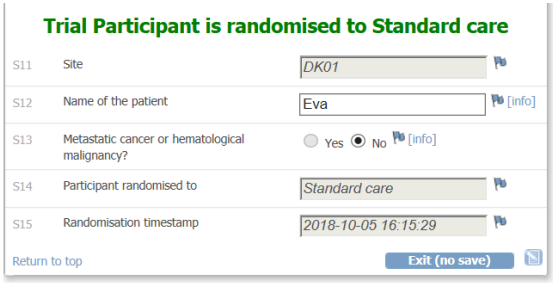
The CLASSIC trial will include 1554 patients with septic shock in intensive care units in Europe

Doctors' responsibility in CLASSIC

Screening
When a patient admitted/planned admitted to your ICU meets the inclusion criteria (see the pocket cards), go to www.cric.nu/classic to screen the patient for enrolment.
Please screen the patient even if you know that she/he will be excluded.

Randomisation
Remember to always obtain informed consent according to national regulations.

If all inclusion- and no exclusion criteria are met the patient can be randomised.
Click the button 'Perform randomisation' and the allocated trial group (IV-fluid restriction or standard-care) will appear.
The patient is now enrolled in the CLASSIC trial.



Note in the patient file and other relevant files that the patient is enrolled in the CLASSIC trial and note his/her group allocation.

During the intensive care stay
The allocated treatment continues as long as the patient is in the ICU to a maximum of 90 days. If the patient is readmitted to the ICU or transferred to another ICU participating in the CLASSIC trial, the allocated treatment intervention continues.
All other interventions and procedures follow normal routines.

About the CLASSIC trial

Background
Septic shock is characterised by infection and circulatory failure and is often fatal.
Traditionally, IV fluids are used to optimise the circulation, and the use of higher volumes is recommended in guidelines. But there is no high-quality evidence to support this, and the balance between benefits and harms of different IV-fluid volumes is unknown.

Methods
1554 ICU patients with septic shock will be randomised to

either
- Restrictive IV-fluid therapy

or
- Standard-care IV-fluid therapy

The detailed criteria for fluid administration are presented in the pocket cards.
All other interventions and procedures will follow normal routines.

Results
We assess 90-day mortality, serious adverse events, serious adverse reactions to IV crystalloids, days alive without life support and days alive and out of hospital. At 1 year we assess vital status, health-related quality of life and cognitive function.

Funding
The trial budget is 1.6 million euro and is funded by the Novo Nordisk Foundation and Sofus Friis' Foundation.

Ethics
The trial is approved by relevant national health authorities and ethics committees. Informed consent must be obtained according to national regulations.

For more info visit
www.cric.nu/classic

Nurses' responsibility in CLASSIC

The CLASSIC trial assesses two different IV-fluid strategies in patients with septic shock. Therefore, we rely on ICU nurses to enforce the treatments especially in the restrictive study group where no IV-fluids should be given unless:

1) **Severe hypoperfusion (IV fluid bolus 250-500mL may be given):**
   - Lactate ≥4 mmol/L **OR**
   - Mean blood pressure < 50 mmHg **OR**
   - Mottling beyond the kneecap **OR**
   - Urinary output < 0.1mL/kg/h, but only in the first 2 hrs after randomisation
2) **Overt fluid losses (e.g. vomit). IV fluids may be given to correct the loss, but not above the volume lost**
3) **Contraindications or failure of the enteral route. IV fluids may be given to**
   - Correct electrolyte deficiencies
   - Ensure total input of 1L per day (incl. fluids with medication and nutrition)

In the standard-care group there is no upper limit for IV or enteral fluids. Deviations from the protocol should only occur in correspondence with the national or coordinating investigator.

Trial documents

The trial protocol and other relevant trial documents are available at www.cric.nu/classic

Questions?

Call the CLASSIC hotline
(24hrs service)

+45 3545 0606
or e-mail:
classic@cric.nu