ISRCTN22435678 https://doi.org/10.1186/ISRCTN22435678

How to judge for fluids in collapsed patients with severe infection

Submission date	Recruitment status	[ ] Prospectively registered
03/11/2021	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
30/11/2021	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
30/11/2021	Signs and Symptoms	[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Severe infections cause a condition called sepsis. More severe cases start to collapse and require prompt actions. These actions include fluid infusions to maintain organs. The aim of this study is to find out whether the amount of fluid given to collapsed patients with sepsis should be driven by the results of testing, or whether it should be kept as low as possible.

Who can participate?
Patients aged 18 years and over with severe sepsis

What does the study involve?
Participants are randomly allocated to the infusion of fluids according to the results of tests, or to low fluid infusion.

What are the possible benefits and risks of participating?
The possible benefits are keeping organs perfused to improve outcomes. The risks include excessive fluid administration or under-infusion.

Where is the study run from?
Cairo University Hospital (Egypt)

When is the study starting and how long is it expected to run for?
February 2018 to January 2021

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
Dr Walid Mohamed Kamel
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Contact information

Type(s)
Public

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Study information

Scientific Title
Dynamic testing based versus restrictive based fluid administration following early fluid resuscitation in septic shock patients: a pilot study

Study objectives
It is hypothesized that the restrictive fluid protocol was comparable in terms of mortality to the dynamic-based testing for fluid responsiveness protocol, following initial fluid resuscitation in septic shock patients. Secondary outcomes were length of ICU stay, mechanical ventilation and need for dialysis.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 25/02/2018, Critical Care Department, Faculty of Medicine, Cairo University (El Sarayat st., Manial, Cairo, 11562, Egypt; +2 (0)122 7434 117; shereenelgengehy@gmail.com), ref: not applicable

Primary study design
Interventional

Study design
Prospective interventional study

Study type(s)
Treatment

Health condition(s) or problem(s) studied

Septic shock

Interventions
This is a prospective cohort study, recruiting septic shock patients, conducted in the Critical Care Department, Cairo University. All patients are initially resuscitated. Patients are assigned according to physician discretion to the restrictive group (fluid administration with a predetermined rate of 1 ml/kg/hour), or the dynamic-based testing group (fluid administration according to dynamic measures, following the passive leg raising method). A positive response is considered when cardiac output increases by 10%.

Intervention Type
Other

Primary outcome(s)
Mortality measured through documenting mortality cases daily during the whole ICU stay

Key secondary outcome(s)
Measured during the whole ICU stay:
1. ICU length of stay measured through reviewing patient notes
2. Need for renal replacement therapy recorded on a daily basis through daily endorsement sheets and nursing documentation
3. Need for respiratory support recorded on a daily basis through daily endorsement sheets and nursing documentation
4. Need for vasopressors recorded on a daily basis through daily endorsement sheets and nursing documentation

Completion date
31/01/2021

Eligibility

Key inclusion criteria
1. Patients ≥18 years old
2. Diagnosed with septic shock (sepsis with persisting hypotension despite adequate volume resuscitation and/or having a serum lactate level >4 mmol/l (18 mg/dl) requiring vasopressors to maintain mean arterial pressure ≥65 mmHg)

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex

All

Total final enrolment
80

Key exclusion criteria
1. Patients aged under 18 years
2. Refusal to consent
3. Conditions that could affect lactate clearance e.g., hepatic, or renal impairment
4. Alcoholic patients

Date of first enrolment
01/11/2019

Date of final enrolment
30/06/2020

Locations

Countries of recruitment
Egypt

Study participating centre
Cairo University Hospitals
Critical Care Department
Faculty of Medicine
El Saraya Street
Manyal
Cairo
Egypt
11562

Sponsor information

Organisation
Cairo University

ROR
https://ror.org/03q21mh05

Funder(s)

Funder type

Other

Funder Name
Investigator initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analyzed during the current study are/will be available upon request from Dr Walid Mohamed Kamel (walidkamel@cu.edu.eg). Data would be available after publication for 6 months, including data collected during patient evaluation and consents obtained.

IPD sharing plan summary
Available on request