

How to judge for fluids in collapsed patients with severe infection

Submission date 03/11/2021	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 30/11/2021	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 30/11/2021	Condition category Signs and Symptoms	<input type="checkbox"/> Individual participant data <input type="checkbox"/> 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

Contact name

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Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number**ClinicalTrials.gov number**

Nil known

Secondary identifying numbers

Nil known

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

Study design

Prospective interventional study

Primary study design

Interventional

Secondary study design

Non randomised study

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

Not available in web format, please use the contact details to request a participant information sheet. This sheet is in Arabic.

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 measure

Mortality measured through documenting mortality cases daily during the whole ICU stay

Secondary outcome measures

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

Overall study start date

25/02/2018

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

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

80

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

Sponsor details

Critical Care Department
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El Saraya Street
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shereenelgengeehy@gmail.com

Sponsor type

University/education

Website

<https://medicine.cu.edu.eg/index.php/en/>

ROR

<https://ror.org/03q21mh05>

Funder(s)

Funder type

Other

Funder Name

Investigator initiated and funded

Results and Publications

Publication and dissemination plan

Planned publication in a peer-reviewed journal

Intention to publish date

31/01/2022

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