

# How to judge for fluids in collapsed patients with severe infection

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

**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  $\geq 18$  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  $\geq 65$  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