

Finger capillary refilling time variations to evaluate effects of fluid administration in critically ill patients

Submission date 25/02/2021	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 04/03/2021	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 03/03/2021	Condition category Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

For a patient with dangerously low blood pressure, a doctor may order a “bolus” of 1 or 2 litres of IV fluids to be given rapidly to increase the patient’s blood pressure.

Fluid bolus (FB) can improve tissue perfusion (the passage of fluid to an organ or a tissue) in critically ill patients. The central venous-to-arterial carbon dioxide tension difference (PvaCO₂) is a metabolic parameter that is closely related to tissue perfusion during fluid bolus. Tissue perfusion can be also evaluated with finger capillary refilling time (CRT) after firmly compressing the finger tissue. The aim of this study is to evaluate the relation between changes in PvaCO₂ and CRT during fluid bolus.

Who can participate?

Adults with suspected hypovolemia (decrease in the volume of blood, which can be due to blood loss or loss of body fluids) who are being treated in the intensive care unit.

What does the study involve?

Participants will have PvaCO₂ and CRT measured before and after receiving a fluid bolus.

What are the possible benefits and risks of participating?

None.

Where is the study run from?

1. Centre Hospitalier Universitaire Brugmann (Belgium)
2. General University Hospital of Patras (Greece)

When is the study starting and how long is it expected to run for?

October 2020 to September 2023

Who is funding the study?

Investigator initiated and funded

Who is the main contact?

Dr Charalampos Pierrakos, charalampos.pierrakos@chu-brugmann.be

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

ClinicalTrials.gov (NCT)

Nil known

Protocol serial number

1617411780

Study information

Scientific Title

Capillary refill time for the assessment fluid bolus tissue perfusion effects in critically ill patients

Acronym

CaRTFBas

Study objectives

1. Decreases in capillary refill time (CRT) during fluid bolus (FB) are correlated with decrease in central venous-to-arterial carbon dioxide tension difference (PvaCO₂)
 - 2.1. The combination of PvaCO₂ and CRT before FB can predict decreases in PvaCO₂ decreases
 - 2.2. To evaluate changes in CRT in relation to changes in hemodynamic parameters
 - 2.3. Relative decreases in CRT after passive leg raising can be used to identify PvaCO₂ decreases after FB

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved 09/02/2021, CHU-Brugmann Ethics Committee (Place Van Gehuchten 4 - 1020 Bruxelles, Belgium; +3224773916; comite.ethique@chu-brugmann.be), ref: CE2021/29

Study design

Prospective observational cohort

Primary study design

Observational

Study type(s)

Diagnostic

Health condition(s) or problem(s) studied

Hypovolemia (loss of blood volume) in critically ill patients

Interventions

- 1) Passive leg raising manoeuvre if it is possible according to the clinical situation
- 2) Patient's finger will be firmly compressed for 10 sec. The whole procedure will be recorded with a smartphone's video camera regulated to 60 frames per seconds and focused on the patient's finger. CRT measurements will be made before after fluid bolus
- 3) Fluid bolus (FB): 4ml/kg of crystalloids fluids will be given within 20 minutes
- 4) Central venous blood gas analysis before and after FB
- 5) Cardiac echocardiography before and after FB

Intervention Type

Other

Primary outcome(s)

Measured before, during, and after intake of the fluid bolus:

1. Capillary refilling time measured using a chronometer
2. PvaCO₂ measured using blood gas analysis with using blood gas analysis devices (RAPID Point 500®; Siemens Health-care Limited, Germany)

Key secondary outcome(s)

Measured before, during, and after intake of the fluid bolus:

1. Cardiac index measured with transthoracic echocardiography
2. Mean arterial pressure measured using sphygmomanometer

Completion date

01/09/2023

Eligibility

Key inclusion criteria

1. Central venous line present in internal jugular vein and arterial line
2. PvaCO₂ >6mmHg

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Key exclusion criteria

1. Age <18 years
2. Extracorporeal membrane oxygenation (ECMO) support
3. Interventions within 15 minutes before FB: increase inotrope dosage, introduction of mechanical ventilation
4. Arterial or venous PCO₂ >75mmHg before or after FB
5. FB for acute bleeding
6. Admission to ICU or hemodynamic instability for less than 6 hours
7. Interventions (i.e. changes in ventilator parameters, change in the dose of inotropes) within 1h before FB
8. Severe peripheral vasoconstriction or hypothermia: not possible to evaluate peripheral saturation with pulse oximetry

Date of first enrolment

01/03/2021

Date of final enrolment

01/03/2023

Locations**Countries of recruitment**

Belgium

Greece

Study participating centre

Centre Hospitalier Universitaire Brugmann

Place Van Gehuchten 4

Bruxelles

Belgium

1020

Study participating centre

General University Hospital of Patras
University of Patras
University Campus
Patras
Greece
265 04 Rio

Sponsor information

Organisation

Centre Hospitalier Universitaire Brugmann

ROR

<https://ror.org/011apjk30>

Funder(s)

Funder type

Other

Funder Name

Investigator initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan

The current data sharing plans for this study are unknown and will be available at a later date.

IPD sharing plan summary

Data sharing statement to be made available at a later date