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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

Registration date
04/03/2021

Overall study status
Completed

Last Edited
03/03/2021

Condition category
Nutritional, Metabolic, Endocrine

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] 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

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
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

Secondary study design
Cohort study

Study setting(s)
Hospital

Study type(s)
Diagnostic

Participant information sheet
No participant information sheet available

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 measure
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)

Secondary outcome measures

Measured before, during, and after intake of the fluid bolus:
1. Cardiac index measured with transthoracic echocardiography
2. Mean arterial pressure measured using sphygmomanometer

Overall study start date
01/10/2020

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

Age group
Adult

Sex
Both

Target number of participants
100

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 peripheric 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
Bruxells
Belgium
1020

Study participating centre
General University Hospital of Patras
University of Patras
University Campus
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265 04 Rio

Sponsor information

Organisation
Centre Hospitalier Universitaire Brugmann

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Sponsor type
Hospital/treatment centre

Website
https://www.chu-brugmann.be

ROR
https://ror.org/011apjk30

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal.

Intention to publish date
01/06/2023

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