Use of ICM+ for running clinical trials
Experiences from the CPPopt trial COGiTATE

Dr. Ertal Beqiri
erta.beqiri@gmail.com
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CPPOpt Guided Therapy: Assessment of Target Effectiveness
Jeanette Tas on behalf of team

Tuesday 09:10-09:20
Room CAG
Use of ICM+ for running clinical trials

- Interventional multicenter randomized controlled trial
- Based on a parameter that requires real-time data collection and processing
- That requires feedback from the clinical team.

All of the things I will show taking COGiTATE as an example, can be adapted to other trials with different protocols.
Daily life of a COGiTATE researcher
Daily life of a COGiTATE researcher
Local data collection
Local data collection
Start COGiTATE in ICM+ - change project
COGiTATE module in ICM+

Welcome to the COGiTATE study!

The COGiTATE study is a prospective intervention study that will assess the feasibility and effectiveness of autoregulation guided therapy (CPPopt) in severe traumatic brain injury patients.

The patient needs to be randomised into the CPPopt group or the standard of care group (CPP) by the local researchers using an external web based tool.

Please select the correct randomisation group below to continue.
CPOpt arm
CPP review

Bedside monitor

Laptop with ICM+

Clinical trial wizard plugins support
What information at the review?
What information at the review?

Curve fitting criteria

1) Each CPP bin must represent at least 3% of the total data count. In this way, CPP values that are very scarcely represented, likely due to short spikes or drops, but not to the physiological trend, will be disregarded.

2) At least 50% of the data in the time window must be included in the curve fit.

3) A PRx variation of at least 0.2 is mandated (thus rejecting flatter PRx-CPP curves).

4) The PRx range of interest is enforced to be between 0.3 and 0.6: the algorithm will not return any CPPopt value when PRx is always very high (indicating a complete loss of pressure reactivity) or always very low (pressure reactivity preserved at each CPP value).

Exponentially Weighted Average

weight = \( R^2 \text{ full} \times \left\{ \begin{array}{ll} 1, & \text{shape} = P \\ 0, & \text{shape} = NP \end{array} \right. \)

weight = (1 – α)^k
Optimal cerebral perfusion pressure assessed with a multi-window weighted approach adapted for prospective use: a validation study


1Brain Physics Laboratory, Division of Neurosurgery, Department of Clinical Neurosciences, University of Cambridge, UK; 2Department of Physiology and Transplantation, Milan University, Italy; 3Division of Anaesthesia, University of Cambridge, UK; 4Department of Intensive Care, Maastricht UMC, The Netherlands; 5Department of Neurosurgery and Szentagothai Research Center, University of Pecs, Medical School, Pecs, Hungary; 6Department of physiological nursing, university of California, San Francisco, CA 94122, USA; 7Department of Anesthesia, Critical care and Emergency, Spedali Civili University Hospital, Piazzale Spedali civil 1, Brescia 25123, Italy; 8Department of Surgery, Rady Faculty of Health Sciences, University of Manitoba, Canada
Logic for trial assistance
Forms for trial assistance
Simulator

COGiTATE_Simul

Brain Physics Lab
Time settings

Bedside monitor

Laptop with ICM+
New center setting up

Marcel Aries

Erla, are you free? 10:34 pm

We need to set up a new centre for Cogitate 10:34 pm

Could you please do that today? 10:34 pm

They want to start tomorrow 10:34 pm
New center setting up
New center setting up

gesolar_module_v84101
icmp.8.4.4.4
New center setting up
New center setting up
New center setting up
New center setting up
New center setting up
Remote setting up and troubleshooting

Bedside monitors

Laptop with ICM+

Connection
Extras
Help
Feedback

Allow Remote Control
Your ID
251 578 508
Password
hf9f56

Control Remote Computer
Unattended Access
Start TeamViewer with Windows
Grant easy access

Partner ID
1166492095
Remote control
File transfer

Ready to connect (secure connection)
End the study

Please make your decisions considering the overall clinical context

CPP Review

Next review at 10:00:00
Data collection: multicentre collaborative tools

ICU 1
- Bedside monitors
- Laptop with ICM+

Data Upload Form

ICU 2
- Bedside monitors
- Laptop with ICM+

File Server in a coordinating centre

Brain Physics Lab
Data collection: multicentre collaborative tools

- Bedside monitors
- Laptop with ICM+
- ICU 1
- File Server in a coordinating centre
- ICU 2
- Bedside monitors
- Data Upload Form

New Patient

Open/Analyse Old Files
Data collection: multicentre collaborative tools

File Server in a coordinating centre

Bedside monitors

Laptop with ICM+

ICU 1

ICU 2

Data Upload Form
Data collection: multicentre collaborative tools

File Server in a coordinating centre

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Laptop with ICM+

ICU 1

Bedside monitors

Laptop with ICM+

ICU 2

Data Upload Form
Conclusions

- I showed you how we ran a prospective interventional RCT with ICM+: you can do the same for any other trial.
- **ICM+ is not a black box:** it does what you ask it to do! You need to know exactly how it works for your specific project, details are important! In particular if you make interventions based on its functioning
- **Please test** everything!
- The software in this case works as **integrated in a clinical setting:** don’t forget it, make things work together.
- Keep the main actors involved and trained (clinical team) and they will love the study as much as you do 🙂