LIBERATE

Midodrine for the early liberation from vasopressor support in the ICU

NEWSLETTER

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Summer is upon us and we hope everyone has had some time take a break and enjoy the nice weather. Over the past few months the LIBERATE team has continued work on the recruitment and set up of new study sites in Canada and Brazil.

In addition, the LIBERATE Study Website is now live! The website contains study information and most recent versions of documents including but not limited to: the study protocol, CRF, MOP, Pharmacy Manual and approvals.

REMINDERS

Protocol version 4.0 and CRF v8.0 recently received REB approval. Changes to note:

- Addition of a SOFA score at the time of first IP administration
- Co-enrollment information can now be entered at the end of the Outcomes Form
- When documenting data for Vasopressor Therapy, Sedation and Co-interventions, Study Day 1 starts at time of first IP administration and ends at 0659 the following morning. All following study days are from 0700 - 0659

As always, thank you to our recruiting sites for their ongoing work on the study!

FAQs

Q. A study participant is receiving Vasopressin and Dobutamine. Should the study IP be discontinued after both Vasopressin and Dobutamine have been discontinued for 24 hours?

A. *Medications such as Dobutamine and Milrinone are classified as inotropes, not vasopressors. Therefore, in this case, the study IP should be discontinued after only Vasopressin has been discontinued for a 24 hour period.*

Q. Our study patient has been ordered as NPO after developing a GI bleed. How should we proceed with study IP administration?

A. *We recognize that a patient's eligibility may change after study enrollment due to changes in their health status. In this case the study IP will not be given while the patient is NPO. If the NPO order is stopped and the patient is still receiving IV vasopressors, the IP should be restarted and administered until IV vasopressors are discontinued for a continuous 24 hour period. If IV vasopressors were stopped for a continuous 24 hour period during the time the patient was NPO, the study IP should not be restarted. In both scenarios, data collection should continue as per the protocol.*

In both cases the Coordinating Centre should be notified and a protocol deviation form should be completed in the REDCap system.

The LIBERATE Study is supported by the Canadian Critical Care Trials Group, the Alberta Clinical Care Strategic Clinical Network, and the University Hospital Foundation Medical Research and Kaye Fund

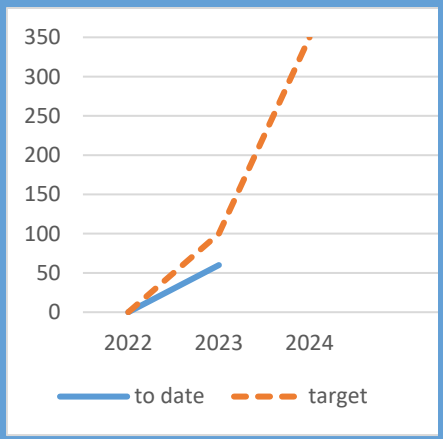
Participating sites

Edmonton - Grey Nuns Hospital
Edmonton - Misericordia Hospital
Edmonton - University of Alberta Hospital

Upcoming sites

Brantford – Brantford General Hospital
Calgary - Rockyview Hospital
Hamilton – St Joseph's Healthcare
Kingston – Kingston Health Sciences Centre
Niagara – Niagara Health Centre
Red Deer – Red Deer General Hospital
Regina – Regina General Hospital
St Albert – Sturgeon Hospital
Toronto - Mount Sanai Hospital
Toronto – Sunnybrook Health Sciences Centre

Study Recruitment



Site	Total enrolled
Grey Nuns Hospital ICU	37
Misericordia Hospital ICU	9
U of A Hospital GSICU	14

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