The PROSPECT Trial

**PRObiotics to prevent Severe Pneumonia and Endotrachael Colonization Trial.**

**Principal Investigator: Dr. Wendy Sligl**

**Primary Research Coordinator: Lorena McCoshen**

**Research Question:** What is the effect of enteral *L. rhamnosus* GG on VAP, other ICU-acquired infections, diarrhea (total, antibiotic associated and *Clostridium difficile*-associated diarrhea), antibiotic use, duration of mechanical ventilation, ICU and hospital length of stay, ICU and hospital mortality compared to placebo among mechanically ventilated critically ill patients? We now hypothesize that *L. rhamnosus* GG will decrease rates of VAP and other ICU-acquired infections, and decrease all-cause, antibiotic-associated diarrhea, and *Clostridium difficile*-associated diarrhea.

**What is the proposed trial design?** A stratified parallel group blinded RCT in which patients will be randomized to placebo or probiotic in a fixed allocation ratio of 1:1 (*L. rhamnosus* GG).

**What is the proposed duration of treatment period?** Patients will receive study product from the time of first administration until:
1) death or discharge from ICU; or
2) isolation of *Lactobacillus* spp. in a culture from a sterile site or if reported as the sole or predominant organism in a culture from a non-sterile site; or
3) censored at 60 days from randomization if patient remains in the ICU.

**What are the outcomes for the PROSPECT Trial?** The primary outcome for the PROSPECT RCT is VAP. Secondary outcomes will include other ICU-acquired infections, diarrhea (total, antibiotic associated and *Clostridium difficile* associated), antibiotic use, duration of mechanical ventilation, ICU and hospital stay, and ICU and hospital mortality.

**What is the proposed sample size for the Main PROSPECT Trial?** The trial will randomize 2650 patients (1325/arm) across 38 ICUs in Canada and the United States of America. Our site plans to contribute a minimum of 60 patients.

PEPTIC Study

**Proton Pump Inhibitor vs. Histamine-2 Receptor Blockers for Ulcer Prophylaxis Therapy in the Intensive Care Unit**

**Background:** 90% of mechanically ventilated patients in Edmonton Zone ICUs receive stress ulcer prophylaxis (SUP). Most receive a proton pump inhibitor (PPI) but many receive a Histamine 2 Receptor Blocker (H2RB). PPIs lower the risk of overt upper GI bleeding compared with H2RBs however PPIs may be associated with greater risk of C. Difficile infection and nosocomial pneumonia compared with H2RB.

**Question:** What is the comparative effectiveness and safety of PPIs versus H2RBs for routine stress ulcer prophylaxis in critically ill mechanically ventilated adults admitted to the ICU?

**Design:** 2 treatment periods of 6 months. During the first treatment period (October 11, 2017 – April 10, 2018) the GSICU will use H2RBs as the default SUP. During the second treatment period (April 11 – October 10 2018) GSICU will switch to PPIs.

A brochure providing study information and an opportunity to ‘Opt out’ of the study will be given to all patients or families along with the GSICU admission brochure.

For more information please contact:
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Recently Completed: EPIC III

The GSICU and Sturgeon ICU participated in **EPIC III on World Sepsis Day, September 13, 2017**! All patients present on or admitted to GS-ICU and Sturgeon ICU on September 13 from 08:00 to September 14 at 07:59 were enrolled into this observational 24 hour point prevalence study.

**Worldwide over 10 000 people were enrolled into the study!**

**A total of 34 patients and 4 patients were enrolled from GSICU and Sturgeon ICU respectively.**

HAPPY HALLOWEEN

Enrollment Update

**ALFSG:** 57  
**BALANCE:** 23  
**FST:** 10

**PEPTIC: enrollment started October 11/17**

**PREVENT:** open to enrollment  
**PROSPECT:** 2

**ROTEM:** open to enrollment  
**STARTT-AKI:** GS-ICU: 16, CV-ICU: 2

To find out more about any study or ways you can be involved please contact Dr. Sean Bagshaw, Director of Research at 780-492-3817 or Nadia Baig, Research Manager at 780-492-9951 or visit our website at [www.ualberta.ca/critical-care/research](http://www.ualberta.ca/critical-care/research)