Hyperbaric Oxygen in Brain Injury Treatment Trial

HOBIT NEWSLETTER

HO$_2$BIT

July 29th, 2022

Great job St. Mary's Medical Center!

1 subject recently enrolled in HOBIT & BioHOBIT

UPCOMING MEETINGS

SIREN Study Coordinator Call
Tuesday, August 2, 2022 1:00pm ET

CQIP
Monday, August 8, 2022 1:00pm ET

SIREN Steering Committee
Wednesday, August 24,2022 12:00pm ET

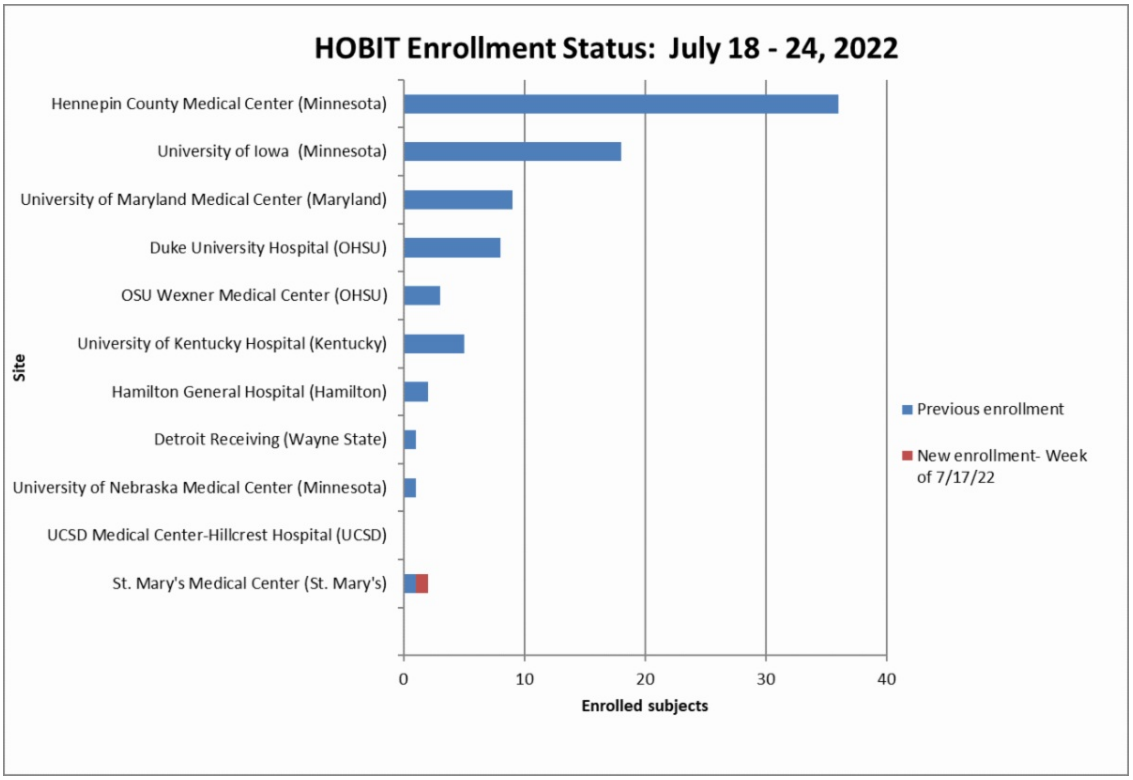
ENROLLMENT

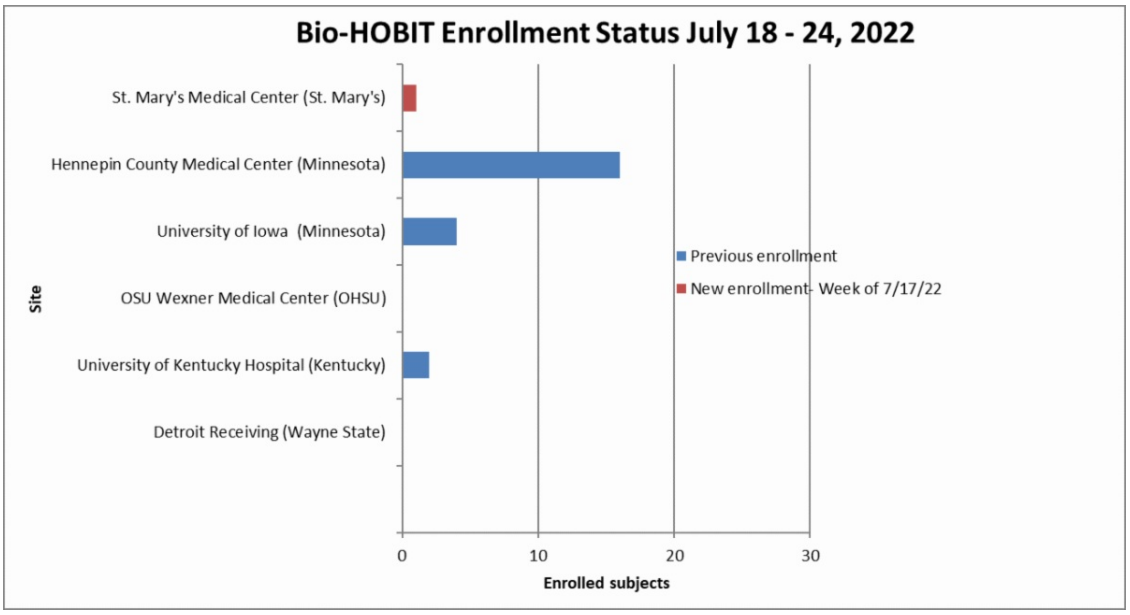
HOBIT: 85 BioHOBIT: 21

** Aim to enroll every HOBIT subject in BioHOBIT **

Recent Enrollers

St. Mary's Medical Center:1





Please continue to screen diligently and enter screen failures in WebDCU

UPDATES & RESOURCES

Reminder of Resource: HYCEP Procedure

Found on hobittrial.org

This is a two-part educational activity:

1. Part one is a video demonstration designed to be a short and effective means of teaching about the risks associated with VAP and demonstrating a procedure to help reduce or mitigate these risks.

HOBIT Trial "HYCEP" Procedure to Reduce Incidents of VAP (Ventilator Associated Pneumonia)

2. Part two is a skills and competency validation that we strongly recommend be completed by all who will be involved with exchanging the ETT cuff from air to normal saline.

Training and Competency Validation for Performing the "HYCEP" Procedures

Recent MOP Updates

Recent changes are highlighted in yellow

3.9.2.3 Anticipated Adverse Events
Page 33

The definition of ventilator acquired pneumonia has been updated to be more consistent with BOOST-3 and the CDC's definition of ventilator associated events.

For purposes of this study, the focus of Anticipated Adverse Events is on Ventilator Associated Pneumonia that is defined as new lung infiltrates on chest X-ray plus clinical evidence that the infiltrate is of an infectious origin (which includes at least 3 of these 4 criteria: new onset of fever, purulent sputum/positive BAL, leukocytosis, and decline in oxygenation) that develops more than 48 hours after endotracheal intubation and requires the initiation of antibiotic therapy. This definition is consistent with the pneumonia definition in the BOOST-3 study and the CDC's definition of ventilator associated event.

3.9.2.5 Guidelines for reporting SAEs
TEMPLATE FOR PNEUMONIA
Page 36

Please see above for the study specific definition of pneumonia SAE

The subject is a {age, gender} who was randomized into the {treatment arm} on {date} and completed {number} treatments on {date}.

The subject began to develop symptoms/signs of pneumonia on {date, time} and they included (note: to meet the study specific definition, signs must start 48 hours after admission):

P/F ratio from ABG – list any that are < 200 {date, time}
Any other signs of decline in oxygenation (i.e. increased PEEP, etc) {date, time}
Elevated WBC counts that are relevant {date, time}
Elevated temperatures (note: must be greater than 38.5 celsius to meet the study specific definition) that are relevant {date, time}
QBAL/sputum culture results {date, time}
CXR results {date, time}

Any treatment for pneumonia (note: must be treated with antibiotics to meet the study specific definition)

State when pneumonia began in relationship to the hyperoxia treatments, for example, the above signs of pneumonia began following Dive #4 which was on

{date, time}.

**If the subject is diagnosed clinically with pneumonia but does not meet the study specific definition, still enter the serious adverse event but for Q15 “Type of event,” choose “None of the above”

HOBIT Trial Contacts: hobit-milestone@umich.edu | hobittrial.org
Emergency 24-Hour Study Hotline: 1-833-HOBIT-PI (833-462-4874)