STRIPES

Steroids in Pediatric Fluid and/or Vasoactive Infusion Dependent Shock

Data Monitoring and Safety Committee (DMSC)

Terms of Reference

Members:

Dr.Dean Fergusson: Epidemiologist, Ottawa Hospital Research Institute (Chair)
Dr. Alex Ahmet: Pediatric Endocrinologist, Children's Hospital of Eastern Ontario
Dr. Ari Joffe: Pediatric Intensivist, Stollery Children's Hospital

Roles and Responsibilities:

The Data Monitoring and Safety Committee (DMSC) is an independent group of experts who will function independently and at arms' length from the STRIPES Study investigators and the steering committee of the pilot study. The purpose of the data and safety monitoring committee is to protect the safety of trial participants, the credibility of the study, and the validity of the study results. The primary responsibilities of the DMSC are to:

1. Review and evaluate the accumulated study data for participant safety each quarter.
2. Review and evaluate all serious adverse events (SAE's) generated from all seven participating centers
3. Make recommendations to the steering committee based on these reviews regarding the continuation, modification, or termination of the trial
4. DMSC members must maintain *strict confidentiality* concerning all study data and results during all phases of DSCM review and deliberations.
5. No member of the DMSC should have direct involvement with the conduct of the study. No member shall have financial, proprietary, professional or other interests that may affect impartial decision-making by the DMSC.

Conflict of Interest:

1. DMSC members will have no major financial or intellectual conflict of interest that could prevent them from objectively reviewing pertinent data and giving advice to the steering committee.
2. DMSC members will disclose to the Chair any other conflicts that they consider relevant.

Items to be reviewed by the DMSC:

1. All serious adverse events (SAE's)- serious adverse event reports will be forwarded to the members of the DMSC by the PI or the study coordinator. It is the responsibility of the PI to ensure that the DMSC is apprised of all new safety information relevant to the study.
2. All study participant deaths
3. Form stopping rules

Note: there will be no interim analysis as this is a pilot study with a small sample size of N=72 patients.

Meetings:

1. Meetings will be scheduled on a regular basis (every 3 months) or more frequently if deemed necessary.
2. Between meetings, the DMSC will receive information concerning post-randomization serious adverse events from all 3 participating centers. Every 3 months, the DMSC will receive tabulated information on SAE's by intervention group and by study center.
3. The DMSC Chair may request a full meeting of the committee at any time.
4. Conference calls or electronic communication are acceptable meeting formats with the agreement of all DMSC members.
5. All 3 DMSC members must be present at the meetings.
6. Minutes will be taken at all meetings and maintained. They will be considered confidential until the end of the study.
7. After each meeting, the DMSC chair will provide the PI with a letter stating the general outcome of the meeting and any suggested changes to the design or conduct of the study. The rationale for recommendations will be included when appropriate. This report will NOT include confidential information. This meeting summary report will be forwarded to the PI within 2 weeks of the meeting.

Safety Decisions:

1. The committee may recommend stopping the study if there are severe adverse events reported by the investigators which are associated with the therapy or study procedures. The committee may recommend stopping the trial only if they find that one strategy is clearly more harmful, however harm must be considered *in light of potential benefit.* This decision will be based on clinical judgment, and not on statistical analysis.
2. When the DMSC decides that a definitive conclusion based on safety issues has been reached, they will immediately notify the PI and the members of the steering committee to discuss the results.