

# SNUG 2

## **AIM:**

To investigate if Glypromate® can reduce any loss of concentration following Cardio Pulmonary Bypass (CPB) surgery.

## **PRIMARY ENDPOINT:**

Co-primary endpoints of cognition and ADL are used in this study. An improvement in cognitive function as measured by the Z score is hypothesized to be similarly reflected in an improvement in the ADL of patients receiving Glypromate

## **SECONDARY ENDPOINTS:**

- Global Summary evaluation of patient's ADL
- Neurological events – cumulative incidence of stroke or TIA will be compared in the Glypromate v Placebo groups at discharge or at 14 days, which ever is earlier, 4-6 weeks and at the 12-14 week time point.
- Change in cognitive scores in 5 domains and 3 ancillary tests (Pegboard Test, Stroop Test and Trail Making Test); will be compared between Glypromate and Placebo at 4-6 weeks and 12-14 weeks.

## **INCLUSION CRITERIA:**

- Scheduled for non-emergency CABG surgery and/or valve replacement/repair with CPB
- Willing to provide written informed consent
- Able and agreeable to undergo all cognitive and ADL testing (ie. understands English, able to read, write, have sufficient motor dexterity and be available for follow up visit at 4-6 weeks and 12-14 weeks postoperatively)
- ≥ 50 years old

## **EXCLUSION CRITERIA:**

- Pre-operative mechanical assist device or IABP inserted for shock/low output syndrome
- Women of childbearing potential or breastfeeding women
- History of or any current condition that in the Investigator's opinion would interfere with study participation or evaluation of results
- Congenital heart disease with risk of polycythaemia, circulatory problems or need for a shunt
- Renal insufficiency (serum creatinine > 180µmol/L [ $> 2\text{mg/dL}$ ])
- Past or present bleeding disorder
- History of organic brain syndrome
- Currently receiving treatment for alcohol or drug abuse
- Currently participating in another investigational drug or device study
- Prior enrolment In this study