Author	*Joëlle De Vriese*	Reviewer(s)	*Véronique Baudewyns*	Approved by	*Jean-Michel Hougardy*
Public	☐ *All* ☐ *Investigators* ☐ *Study Nurse* ☐ *Study coordinator* ☐ *Paramedics* ☐ *Admin Staff*				
Document revision history / Changes-Revision Comment					

Protocol (Acronym): HEPACS

Title: Sécurité de l'administration préopératoire d'hémine en vue de réduire de le risque d'atteinte rénale aiguë après chirurgie cardiaque : une étude pilote randomisée en double aveugle. (Safety of preoperative administration of Hemin to reduce the risk of acute kidney injury after on-pump cardiac surgery :a pilot randomized study in double blind).

Principal Investigator: Prof. Jean-Michel Hougardy, MD, PhD

Erasme EC Reference number: P2014/148

Leading EC: **Comité d'Ethique Erasme-ULB, Route de Lennik 808, 1070 Bruxelles**

EC approval date:

Date of report: 25/07/2017

- **Current Status**
  - The experiment didn't start yet because:
  - The experiment started on 16/01/2015 (Initiation date or 1st "screening" date)

- **Conduct of study from the start or from the last report**
  - The experiment is performed according to the expected design: x YES ☐ NO
    - ✓ Expected patients number on site : 60
    - ✓ Recruitment status on site : 8
      - Screened patients number: 20
      - Enrolled patients number: 8
      - Drop-out/withdrawal patients number: 0
        + reasons if known:
      - Number of patients having terminated the experiment according to the protocol: 8
    - ✓ Total patients (multicentric research if Erasme Sponsor) : 12

- The experiment is temporary stopped: □ YES □ NO

  If yes, specify:

  □ adverse events (please specify) :

  □ technical or practical issues (please specify) :

  □ other (please specify) :

- **The experiment is terminated: x YES** □ NO

  If yes, specify:

  □ adverse events (please specify): none

  □ other (please specify) : none

  □ limited number of recruited patients : Yes; we had too few patients that were eligible. This was leading to the premature closing of the present study. This lack of potential patients is mainly due to the changes in the surgery strategy with time (less severe patients are now selected for that kind of cardiac surgery and more mini-invasive strategies are proposed). Therefore, this study has become unrealistic with that kind of protocol.

  □ according to the study design → End date:

Are the observed adverse events and their severity in accordance with the information provided at time of initial submission? Their was no AE.

□ YES

□ NO (please specify):

- **Additional information/ additional reports to be provided to EC**
  - If no DSUR (from the Sponsor) is provided, please provide a summary of adverse events and adverse outcomes experienced by participants, as well as a summary of unanticipated problems involving risks to participants or others : There were no adverse events that were observed.
  - Please provide a summary of complaints received about the research : There were no complaints.
  - Please provide a summary of amendments and modifications submitted since last report : there have been no amendments or modifications submitted since last contact with the EC.

- Please communicate any relevant recent literature or interim findings that could impact safety of participants : there have been no such findings
- Please provide any relevant multi-center trial reports. There are no relevant multi-center trial reports to provide.

- **Risk/ benefit balance**
  - Is the risk/benefit balance, based on study results, still positive for the participants (according to PI's opinion)?

    x YES

    □ NO (please specify)

The Erasme Hospital EC has received, analyzed and approved the above information on (date) .....