Serious Adverse Event (SAE) Report Form

A randomized trial of doxycycline chemoprophylaxis for the prevention of sexually transmitted infections in gay, bisexual and other men who have sex with men (gbMSM)

Principal Investigator: DR Joseph Cox

Date: 04 NOV 2024

Participant ID: 102006

1. SAE Onset Date: 08 OCT 2024 (dd/mmm/yyyy)
2. SAE Stop Date: 15 OCT 2024 (dd/mm/yyyy)
3. Location of serious adverse event: McGill University Health Center
4. Was this an unexpected adverse event? Yes ☒ No ☐
5. Brief description of participant(s) with no personal identifiers:
   Sex: F ☐ M ☒ ☐ Transgender ☐ Other (please specify): _____
   Age: 56
6. Brief description of the nature of the serious adverse event (attach description if more space needed): Perforated rectum due to sexual trauma
7. Category of the serious adverse event:
   - ☐ death – date __/___/___(dd/mmm/yyyy)
   - ☒ life-threatening
   - ☒ hospitalization-initial or prolonged
   - ☐ disability / incapacity
   - ☐ congenital anomaly / birth defect
   - ☐ required intervention to prevent permanent impairment
   - ☐ other: _____
8. Intervention type:
   - ☐ Medication or Nutritional Supplement: specify _____
   - ☐ Device: Specify: _____
   - ☒ Surgery: Specify: Stoma
   - ☐ Behavioral/Life Style: Specify: _____

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9. Relationship of event to intervention:

- [x] Unrelated (clearly not related to the intervention)
- [ ] Possible (may be related to intervention)
- [ ] Definite (clearly related to intervention)

10. Was study intervention discontinued due to event? [ ] Yes [x] No

11. What medications or other steps were taken to treat serious adverse event?
ANTIBIOTICS, SURGERY

12. List any relevant tests, laboratory data, history, including preexisting medical conditions
PATIENT CHART TO BE REQUESTED FROM TREATING FACILITY

13. Type of report:

- [x] Initial
- [ ] Follow-up
- [ ] Final

Signature of Principal Investigator: _____ Date: 04 NOV 2021

DR BERTRAND LEBOUCHÉ FOR DR Joseph Cox