CTN Study Reporting Template: ~~Final~~ Study Report

CTN STUDY REPORTING TEMPLATE: ~~FINAL~~ STUDY REPORT	
STUDY INFORMATION	
CTN or CTNPT Study #: CTN PT 047	Date: 10 Jun 2024
Study Title/Name: **Influence of a 3-month letermovir treatment on gut inflammation in ART-treated HIV-infected persons in an open labelled controlled randomized study**	
Principal Investigator(s): Dr. Jean- Pierre Routy	
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STUDY OVERVIEW	
Study is open to enrolment. We already have 39 participants and all recruitment targets are being met. The enrolment period ends in June 2025 and the study is supposed to end by September 2025.	
CTN FUNDING	
1. Did the CTN provide funding? X Yes ☐ No (if no, proceed to Question 3) 2a. Are the study financial statements attached? X Yes ☐ No (if no, describe why)	
2b. Please describe how the funds provided by the CTN have been used: Pharmacy Review Fee **$1,090.00** Core & platform services **$2,003.00** Patient compensation **$18,000.00** Total **$21,093.00**	
KNOWLEDGE TRANSLATION ACTIVITIES	

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2. Please provide a list of publications, presentations, abstract and conference submission details that have been completed to date and plans for future publications/abstract submissions (include the estimated date of completing final manuscript). This may be provided in a separate attachment. If available, please include the Digital Object Identifiers (DOIs) for publications.

Royston L, Isnard S, Berini CA, Bu S, Lakatos PL, Bessissow T, Chomont N, Klein M, Lebouché B, de Pokomandy A, Kronfli N, Costiniuk CT, Thomas R, Tremblay C, Boivin G, Routy JP. Influence of letermovir treatment on gut inflammation in people living with HIV on antiretroviral therapy: protocol of the open-label controlled randomised CIAO study. BMJ Open. 2023 Jan 23;13(1):e067640. doi: 10.1136/bmjopen-2022-067640. PMID: 36690406; PMCID: PMC9872486.

3a. Has the CTN been acknowledged in all publications connected to this study? ☒ Yes ☐ No (if no, describe why)

3. Please provide details on other knowledge translation activities, such as media interviews, webinars, articles in newsletters, community presentations, etc.:

No knowledge translation activities performed yet.

COLLABORATIONS

4. Please summarize activities conducted with partners and collaborators over the course of the study:

No other sites had been opened since one of the sites required the total budget we had for the whole study.

5a. Have there been any new collaborators, partners, or external funders (not listed in the original submission documents)? ☐ Yes X No

If yes, please name them here:

STUDY IMPACT

5. Please describe the impact and significance of this study:

The effects of CMV latent infection has been widely reported and include persisting inflammation, gut leakage, decreased response to vaccines and to pathogens. As such, a potential beneficial effect of letermovir on those parameters is expected, which is particularly meaningful in PLWH. Altogether, findings from this study may clarify the influence of CMV on health, and help to improve treatments for PLWH.

Please use this space to provide any further details you need to report: