**ANRS 176 RHIVIERA-02**

*(Informations destinées aux participants)*

| | |
|---|---|
| **Title** | A randomised phase II placebo-controlled trial of ART plus dual long-acting HIV-specific broadly neutralising antibodies (bNAbs) vs ART plus placebo during primary HIV-1 infection to study the impact on post-treatment HIV control. |
| **Sponsor** | Inserm-ANRS MIE |
| **Start of inclusions** | **March 2024** |
| **Inclusions status** | Ongoing |
| **End of the study** | **January 2030** |
| **Number of participants** | **69** |
| **Objectives** | |

**Main**: Evaluate if the administration of a treatment consisting of dual long-acting HIV-specific broadly neutralizing antibodies (3BNC117-LS & 10-1074-LS (bNAbs)), in combination with an antiretroviral therapy (ART) in individuals with primary HIV-1 infection (PI) when compared to ART only (with neutralizing antibodies or placebo) will favour a period of HIV-1 remission when ART is interrupted 52 or 76 weeks later.

**Secondary:**

- Evaluate the tolerability of intravenous (IV) infusion of bNAbs;
- Study the clinical, immunological and virological evolution of participants;
- Baseline factors associated with plasma Viral Load (VL) control during ATI;
- In social sciences, explore :
    - Expectations and motivations related to participation in the clinical trial and their evolution after having experienced such a participation,
    - anticipation and understanding of risks and benefits related to participation,
    - evolution over time of participation experience and of satisfaction with the information delivered,
    - experience and perception of the ATI period, with an emphasis on its impact on prevention behaviours and sexual quality of life,
    - reasons and experience related to refusal of participation.

Summary



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## 1. Information for participants

**A – Overall research results**

Summary of results: not available (inclusions in progress)

References: not available (inclusions in progress)

**B – Secondary reuse of data and samples**

This section concerns participants who have been included in the research and have agreed to the re-use of their data. Through its website and the present document, the research sponsor informs you of projects related to the secondary reuse of your data and/or samples.

**B1. For non-initiated or ongoing projects listed below only**, you have the option of objecting to the secondary use of your data. To do so, please send an e-mail to **dpo@inserm.fr**, giving the name of the trial and the title of the project for which you object to the re-use of your data, no later than one week before the planned date of completion of the project.

Non-initiated projects

| | |
|---|---|
| Project title | |
| Project synopsis | |
| Estimated completion date | |
| Data recipients in France | |
| Data recipients abroad | |
| Identity and data processor | |
| Transfer of data and/or samples | |
| Conservation period of data and/or samples | |
| Data category | |

Initiated projects

| | |
|---|---|
| Project title | |
| Project synopsis | |
| Estimated completion date | |
| Data recipients in France | |
| Data recipients abroad | |
| Identity and data processor | |
| Transfer of data and/or samples | |
| Conservation period of data and/or samples | |
| Data category | |

**B2.** It is not possible to object to **completed projects.**

Completed projects

| | |
|---|---|
| Project title | |
| Project synopsis | |
| Project start dates | |
| Data recipients in France | |
| Data recipients abroad | |
| Identity and data processor | |
| Transfer of data and/or samples | |
| Conservation period of data and/or samples | |
| Data category | |
| Overall project results | Publication or summary of results |