Aims
In this context, the ANRS-APSEC study is in line with the IAS Towards an HIV Cure Scientific and therapeutic progress allow to consider HIV cure-related clinical trials (HCRCTs) towards transitory or definitive antiretroviral treatments (ART) interruption.

The three broad aims of the ANRS-APSEC study are to:

1. Identify the various motivations and barriers which might influence patients’ willingness to participate in HCRCTs or physicians’ willingness to propose such cure trials.
2. Define acceptable therapeutic strategies.
3. Establish recommendations for the design and management of future HCRCTs that will take into account all the stakeholders’ viewpoints.

Methods

Phase 1 – to allow classification of motivations and barriers into 7 dimensions developed into 33 statements

Phase 2 – Q-methodology

- 33 statements to be ranked (1 - 4, sort facial to computer assisted interview)
- Treatment modalities and follow up (5 statements)
- Risk, adverse effects and quality of life (6 statements)
- Patient-physician relationship (3 statements)
- Belief and attitudes (4 statements)
- Benefits (7 statements)
- Information (4 statements)
- Target population (4 statements)
- Factorial analysis to identify the structure of the main viewpoints

SERA: Jointly funded by the national research framework initiative that supports social sciences research around ethical questions.

Conclusions

A large majority of patients (97.5%) and HPs (93%) declared they would participate to HCRCT.

According to the viewpoints expressed:

- The dimensions at stake, and thus barriers and motivations, differed
- They are not specific to the studied populations

Question the strategy to adopt in the design of the future HCRCT to enable a better acceptability and participation

- Focusing on the most motivated viewpoints or corresponding to the greatest number?

Study design

Phase 1: Qualitative

• To observe knowledge building giving access to representations and collective construction of sense
• Individual interviews and collective discussions (focus groups)

Phase 1: Ideal

• To describe the structure of the main patients’ and HPs’ viewpoints towards willingness to participate/proposal HCRCT
• Q method – ranking of statements according to one’s viewpoint (preferences, judgement, etc.)

Phase 3: Qualitative

• To determine the most relevant HCRCT protocols according to patients’ and HPs’ viewpoints
• Conjoint-based analysis: assessing the relative tolerance of desire for particular attributes of trial strategies based on expectations and perceptions

Study sample

• Participants (n=22)
  - HIV patients (stable ART for 6 months, undetectable viral load, CD4 >500)
  - Health professionals (physicians, nurses, clinical research technicians)
  - 5 French infectious disease units: CHU Paris Sud (Bicêtre), Hôpital St-André (Bordeaux), Centre Inserm/CEA UMR 1184, Le Kremlin Bicêtre, Hôpital St-Marguerite (Marseille), CHU Nantes (Nantes), Hôpital Foch (Suresnes)

Factorial analysis results

• 4 viewpoints identified for each population (patients / HPs)
- Expressing a gradient of acceptability
- Representing a large part of the expressed variability
- 62% for patients
- 61% for health providers
- Not strictly superimposed upon population analysis
- Consensual statements

- Specific viewpoints
- The three category of health providers were correlated with their four HP viewpoints.

Population specific viewpoints

HP
Benefits centered 13% variability

- Motivation: to avoid long-term ART side effects for patients
- Need of direct benefit for patients, of regular and closely monitored follow-up
- Not of HPs (as risk of side effects can be considered "normal" for ART)
- Refusal of HCRCT with ART interruption 6 months at the end
- Acceptation of constraints and side effects (except if irreversible)
- Support priority to prevention and access to ART to everyone

Patients
Conditioned participation and access to all of HCRCT 17% variability

- Motivation: to forget the disease with time
- Acceptation of side effects (except if irreversible or affecting vital organs) and constraints (except hospitalization for administration of the innovative treatment)
- Need of a direct benefit and a regular and closely monitored follow-up
- Expect a clear information about the treatments
- Need for access to HCRCT for the highest number of persons

HP
Motivation centered 16% variability

- Not of HPs but of patients
- Motivation: to avoid long-term ART side effects for patients and to forget the disease with time
- Side effects and constraints accepted, including ART interruption 6 months at the end
- Wish of a greater feedback on the HCRCT results

HP
Willingness not engaged Patients 16% var.

- Motivation: to avoid long-term ART side effects for patients and to forget the disease with time
- Side effects and constraints accepted, including ART interruption 6 months at the end
- Willingness to participate if the target population is engaged

HP
Retention and way of life centered

- Not of HPs but of patients
- Patients not engaged in HCRCT
- Concerned with information to allow medical advances for future generations
- Priority to the way of life: rejection of constraints and overall of side effects

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Discussion

- Key point: the patient-physician relationship
- Emphasises the high confidence from patients towards physicians: "If the physician proposes it to me, it means it's good for me"

- Some concordances:
  - Importance to participate to HIV research
  - HIV physicians must be confident in HCRCT
  - Wish of a regular feedback from the physicians on HCRCT results during the trial

- Some differences:
  - Higher confidence in HCRCT among patients compared to HPs professionals
  - Priority to research on curative treatments vs priority to prevention and access to ART for all
  - Selection of the target population seen as a restriction to access care vs as a clinical condition
  - Patients more willing to accept some side effects than HPs