

EXCLUSION OF PEOPLE LIVING WITH HIV FROM ONCOHAEMATOLOGICAL CLINICAL TRIALS WITH IMMUNE CHECKPOINT INHIBITORS

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BACKGROUND AND IMPORTANCE

Previous research highlighted that people living with HIV (PLWHIV) are frequently excluded from clinical trials (CT) aimed at cancer treatment with immune checkpoint inhibitors (ICI), even if HIV is well controlled. Scientific societies and regulators have issued recommendations to correct this, and real-life evidence supports that the use of ICI in PLWHIV appears to be safe. There is no recent data on whether this trend has changed.

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AIM AND OBJECTIVES

To determine whether HIV infection is an exclusion criterion in oncohaematological CT involving ICI available at our centre.

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MATERIAL AND METHODS

- » Observational, single-centre, retrospective study, which included all oncohaematological CT whose experimental intervention involved the use of ICI initiated in a tertiary hospital from January 2018 to December 2022. Expansion studies were excluded.
- » The following variables were collected: neoplasm, locations (unicentre/multicentre; national/international), ICI, intervention (monotherapy/combination), control (yes/no), phase, clinical context (adjuvant/neoadjuvant/locally advanced/metastatic/haematological malignancy with curative intent/haematological malignancy with palliative intent), intention (curative/palliative), inclusion criteria for PLWHIV (explicitly excluded/conditional inclusion/not mentioned) and, among conditional inclusion, conditions established (viral load/antiretroviral treatment/lymphocyte count).
- » Data were extracted from clinicaltrials.gov, the EU Clinical Trials Register and the Spanish CT Register.

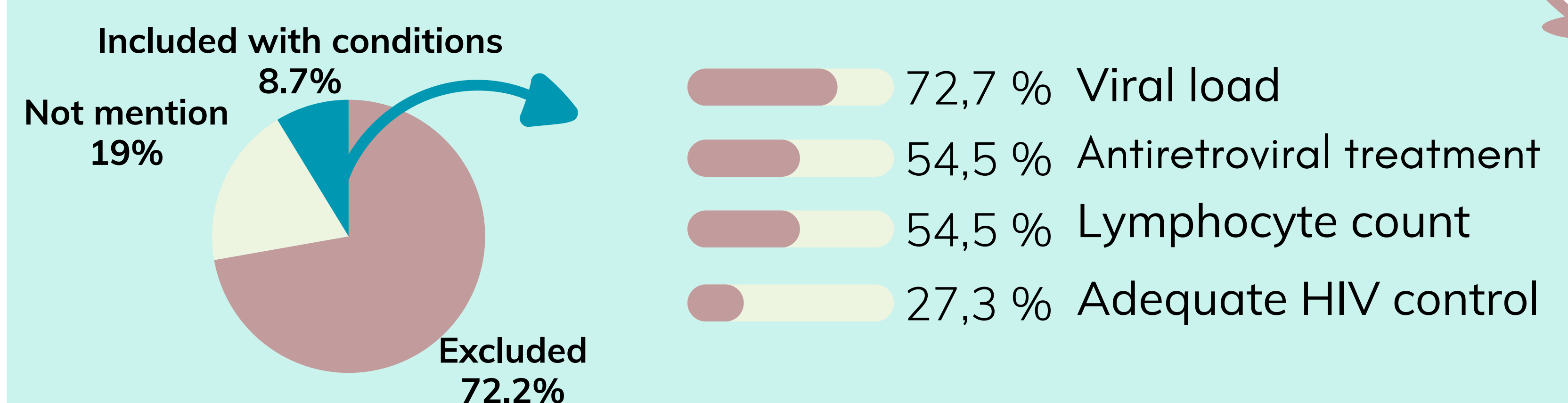
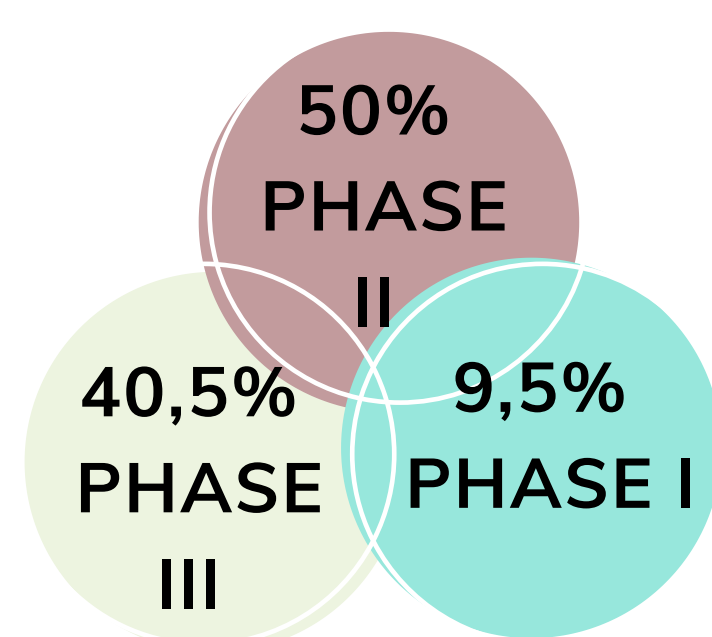
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RESULTS

One hundred and twenty-six CTs were identified, of which 123 (97.6%) involved solid tumours. The most studied neoplasms were lung cancer (n=17; 13.5%), basket trials (n=16; 12.7%) and melanoma (n=14; 11.1%). The intervention consisted of ICI combined with other agents (n=89; 70.6%), ICI monotherapy (n=25; 19.8%), and ICI dual therapy (n=22; 17.5%). **Pembrolizumab** was the most frequently studied ICI (n=34; 27.0%), followed by **atezolizumab** (n=22; 17.5%) and **nivolumab** (n=20; 15.9%). Most were conducted in the metastatic setting (n=98; 77.8%) and with palliative intent (n=103; 81.7%).

126 CLINICAL TRIALS IDENTIFIED

- 90,5% International
- 90,5% Multicentre
- 90,5% Controlled



Inclusion of PLWHIV in oncohaematological CT

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CONCLUSIONS

PLWHIV are frequently excluded from oncohaematological CTs testing ICI.

