Paca-Corse
DISPOSITIF SPÉCIFIQUE RÉGIONAL DU CANCER

# MOIO

# Etude de phase III randomisé évaluant un traitement d'immunothérapie (IO) standard par des inhibiteurs de point de contrôle, par rapport à une intensité de dose réduite d'IO, chez des patients atteints d'un cancer métastatique en réponse après 6 mois d'IO standard

**Phase :** III

**Type d'essai :** Académique / Institutionnel

**Etat de l'essai :** Ouvert

## Objectif principal

Progression-free survival (PFS).

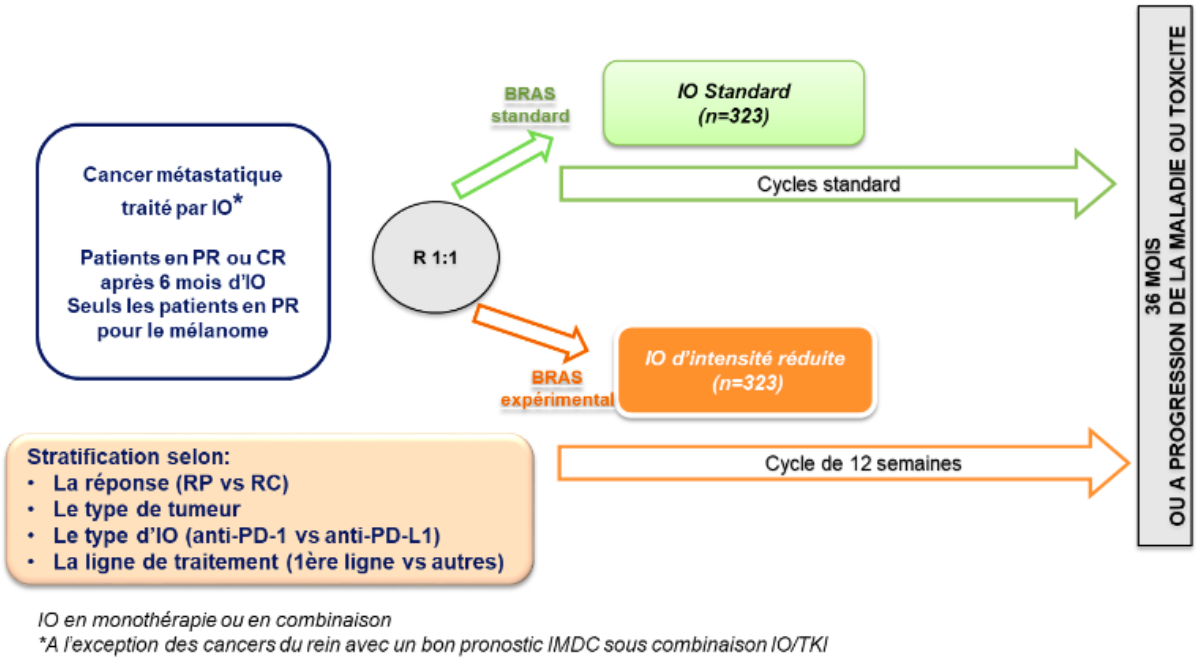
## Objectifs secondaires

Cost-effectiveness analysis of the proposed therapeutic strategy.
Immune progression-free survival (iPFS).
Objective response rate (ORR).
Overall survival (OS).
Duration of response (DoR).
Quality of life questionnaire.
Core 30 (QLQ-C30).
The Developed 5-level version of EQ-5D (EQ-5D-5L) questionnaire.
Hospital anxiety and depression scale (HADS).
Fear of relapse questionnaire.
Safety profile.

## Résumé / Schéma de l'étude

Experimental : Experimental arm = Reduced dose intensity of IO : IO will be administered every 3 months (at the same dose levels) until disease progression, unacceptable toxicity, death or patient's choice or investigator's decision.

No Intervention : Control arm = Standard IO : Continuation of IO at the same dose levels and rhythmicity until disease progression, unacceptable toxicity, death or patient's choice.




*IO en monothérapie ou en combinaison*
**A l'exception des cancers du rein avec un bon pronostic IMDC sous combinaison IO/TKI*

## Critères d'inclusion

1 Patients must have signed a written informed consent form prior to any trial specific procedures.

2 Patient aged ≥ 18 years old.

3 Initial metastatic disease histologically confirmed including : lung cancer, renal cell cancer, head and neck cancer, bladder cancer, triple negative breast cancer, Merkel cancer, hepatocellular carcinoma, and melanoma.

4 Patients in partial or complete response after 6 months of standard immunotherapy (whatever the line of therapy) according to the RECIST (confirmed by local radiological assessment). For metastatic melanoma only patients in partial response.

5 Eligible to maintain the same standard IO treatment.

6 Patient with Eastern cooperative oncology group (ECOG) performance status ≤ 1.

7 Patients with brain metastases are allowed, provided they are stable according to the following definitions : treated with surgery or stereotactic radiosurgery and without evidence of progression prior to randomization and have no evidence of new or enlarging brain metastases.

8 Patients treated by IO previously combined with chemotherapy are allowed.

9 Patients with Tyrosine Kinase Inhibitor (TKI)-IO or pemetrexed-IO or bevacizumab-IO are allowed.

10 Evidence of post-menopausal status, or negative urinary or serum pregnancy test for pre-menopausal patients.

11 Both sexually active women of childbearing potential and males (and their female partners) patients must agree to use adequate contraception method for the duration of the study treatment and after completing treatment according to the most recent version of the IO Summary of product characteristics (SmPC).

12 Patient is willing and able to comply with the protocol for the duration of the trial including undergoing treatment and scheduled visits, and examinations including follow-up.

13 Patient must be affiliated to a Social Security System.

## Critères de non-inclusion

1 Metastatic melanoma in complete response.

2 Metastatic renal cell carcinoma with International Metastatic Renal Cell Carcinoma Database (IMDC) favourable-risk treated TKI/IO combination.

3 Hematologic malignancies (leukaemia, myeloma, lymphoma…).

4 Active infection requiring systemic therapy.

5 Patients enrolled in another therapeutic study within 30 days before the inclusion in and during MOIO study.

6 Patient unable to comply with study obligations for geographic, social, or physical reasons, or who is unable to understand the purpose and procedures of the study.

7 Person deprived of their liberty or under protective custody or guardianship.

## Calendrier prévisionnel

Lancement de l'étude : Mars 2022
Fin estimée des inclusions : Mars 2025
Nombre de patients à inclure : 646

## Etablissement(s) participant(s)

### > Centre Antoine Lacassagne (CAL)

(06) ALPES-MARITIMES

Dr. Delphine BORCHIELLINI
Investigateur principal

### > Institut Paoli-Calmettes (IPC)

(13) BOUCHES-DU-RHÔNE

Dr. Gwenaelle GRAVIS
Investigateur principal

### Hôpital d'Instruction des Armées Sainte-Anne

(83) VAR

Dr. Laurys BOUDIN
Investigateur principal

**> Sainte-Catherine Institut du Cancer Avignon - Provence (ICAP)**

(84) VAUCLUSE

Dr. Werner HILGERS
Investigateur principal

## Promoteur(s)

### UNICANCER

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**< PRÉCÉDENT** RETOUR AUX RÉSULTATS **SUIVANT >**