

Frequently Asked Questions:

Yearly ImmunoSABR Consortium meeting
4 December 2020

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1. If we want to irradiate the primary tumour, can we include the patient in immunoSABR?

Answer:

- If you treat the primary with radio-chemotherapy, you have to wait 4 weeks after the end of the radio-chemotherapy to randomize the patient in order to avoid lymphopenia that would suppress the abscopal effect of the IO. If you feel the irradiation of the metastatic lesion can wait and it would be beneficial to wait in order to give the patient access to a promising drug, you can include him.
- If you treat the primary with radiotherapy alone you can directly include the patient if, the irradiation field is small and if you use hypofractionation. We advise you to wait a few weeks after the end of the irradiation for the lymphopenia to be resolved, if the irradiation fields are large and you use 2 Gy per fractions.

2. Can we include a patient if there is no measurable lesion?

Answer: Yes, absolutely the main endpoint is PFS not RECIST

3. Is "progression" an exclusion criterion?

Answer: Not anymore according to the revised protocol. If it is a threatening lesion consider to irradiate it?

4. Can the systemic treatment occur in another centre, not registered in ImmunoSABR, if the patient is randomized in the control arm?

Answer: Yes absolutely. For the sake of clarity, this is not true if the patient is in the experimental arm. The combination of Pembro-Darleukine or Darleukin alone must occur in the registered center covered by the insurance.

5. When should we give Pembro or any checkpoint inhibitor?

Answer: It should not be given on day 5 (Friday) and you should always administer the Darleukin over 3 hours and give Paracetamol (or Ibuprofen or Metamizol). There are three possibilities

- a) Give it on day 1 (Monday)
- b) Give it on day 8 (the following Monday)
- c) Give it one week after the last Darleukin administration

6. Is the tumour biopsy still useful? How should it be given?

Answer: Yes it is very useful. The group of Sine Hadrup has a beyond the state of the art technique and promising data. As we need to extract DNA and RNA we need it frozen or in RNA later.

7. Can we do the CT with contrast one week after L19-IL2 injection?

Answer: Yes, we allow this and we will make an amendment

8. When will the project end?

Answer: *The New end-date is 30/06/2023.*

9. If I include more patients, will my center get more funds?

Answer: Yes. the funding is proportional to the number of patients included in the trial. The reverse is also true, should you include fewer than the agreed number of patients your center will receive less money.

10. What are the URL's for the ImmunoSABR social media links

<https://www.facebook.com/immunosabr>

<https://twitter.com/ImmunoSabr>

<https://www.linkedin.com/company/immunosabr/?viewAsMember=true>