agence de la biomédecine

Recommendations regarding the use of hematopoietic stem cells or blood mononuclear cells with regard to the risk of infection with the SARS-CoV-2 virus.

March 20th, 2020 update

Countries and territories identified as at risk of SARS-CoV-2 infection

(See attached the 3rd stage algorithm)

Worldwide

For the world, refer to the updates on the ECDC website :
https://www.ecdc.europa.eu/en/areas-presumed-ongoing-community-transmission-2019-ncov

France

For France, refer to the updates on the Santé publique France website :
https://www.santepubliquefrance.fr/maladies-et-traumatismes/maladies-et-infections-respiratoires/infection-a-coronavirus/articles/infection-au-nouveau-coronavirus-sars-cov-2-covid-19-france-et-monde

The symptoms described for a SARS-CoV- 2 infected person mainly evoke a febrile respiratory infection. Some of the cases present with respiratory difficulties and pulmonary abnormalities. For the most severe cases, the patient might present with acute respiratory distress syndrome, renal failure or multi visceral failure, which might be lethal.

Available data, enabled to identify a simple form with a favorable development without any major parenchymal symptom and a severe form, in which one may observe a worsening on the seventh day afterinfection, a bilateral parenchymal infection with ARDS risk, a sepsis with bacterial and fungal secondary infections.

A donor with uncontrolled infection at the time of the donation must be deferred (decree of November 4th 2014 regarding the selection of organs, tissues and cells).

The recommendations for the donor clinical selection are as follows, without predjudice to any other measures concerning other infectious agents (malaria, Chagas, …) :

➢ **Instructions for the donor selection (3th phase : epidemia)**

- **Every donors must be tested.**
- Donor's medical history regarding a contact with SARS-CoV-2 positive patient must be checked.

➢ **Instructions for the donor qualification (3rd stage: epidemia)**

In emergency situations which would not allow postponement, the donor biological eligibility is carried out by testing the donor for the presence of the virus SARS-CoV-2 with gene amplification (RT-PCR) on a naso pharyngeal swab and, if possible, on a blood sample (whole blood, serum or plasma).
These samples have to be collected ideally :

- At the time of the donor qualification before the beginning of the recipient conditioning regimen,
- At the closest moment of the collection.

Results must be transmitted to the graft team as soon as possible.

(a) For tests done before the beginning of the recipient conditioning regimen :

[1] If the results are negative on the nasopharyngeal swab (and on the blood test if carried out), both collection procedure and graft procedure can continue.

[2] If the results are positive (on at least one of the tests, if both –on nasopharyngeal swab or blood sample- were done), both physicians in charge of the recipient and of the donor must contact an infectious disease specialist. Taking the risk benefit ratio of the recipient, the transplant can be maintained or postponed. If the final decision is to do a transplant, a clinical justification and an appropriate follow up are mandatory. The recipient's information and informed consent must be recorded in medical file.
For the donor
The collection will happen according to the medical facility's rules regarding this infectious risk.

(b) For tests done at the closest moment before the transplant

[1] If the results are positive (on at least one of the tests, if both –on nasopharyngeal swab or blood sample- were done), teams are notified about the risk the presence of SARS CoV-2 represent and they assess the risk benefit ratio of the transplant for the recipient. The search of an alternative donor must be done urgently if possible. If the final decision is to do a transplant, a clinical justification and an appropriate follow up are mandatory. The recipient's information and informed consent must be recorded in the medical file. The collection will happen according to the medical facility's rules regarding this infectious risk.

[2] If the results are not available before the transplant and if the transplant is maintained, a clinical justification and an appropriate follow up are mandatory. The recipient's information and informed consent must be recorded in the medical file.
In this situation, and in order to have the results before the transplant, the conditioning regim may be postponed and the graft frozen.

- **For donors who have had a confirmed SARS-CoV-2 infection,** the collection will be possible 28 days after resolution of symptoms. Specific monitoring of the recipient will be set up.