Impact of COVID-19 vaccination in AA/PNH patients

EBMT-SAAWP
Non-Interventional Prospective Study

CRF

STUDY PERIOD

FROM JANUARY 1ST 2021

Patient Identification

EBMT centre number (CIC) _____

Hospital _____

City / Country _____

Contact person _____

Contact person e-mail _____

Patient Unique Identification Code (UIC) _____

Hospital Unique Patient Number (UPN) _____

Date of birth _____ *(yyyy-mm-dd)*

Sex ☐ Male ☐ Female

Please note: hematologic stem cell transplantation (HSCT) is an exclusion criterion for this study. If the patient has received a HSCT, the patient is not eligible for this study.

Aplastic anaemia (AA)

Diagnosis	**Date of diagnosis**
☐ Very severe AA	_____ *(yyyy-mm-dd)*
☐ Severe AA	_____ *(yyyy-mm-dd)*
☐ Non severe AA	_____ *(yyyy-mm-dd)*

Please continue on the next page

Current treatment for AA (tick all that apply)

Drug name	Dose/schedule	Start date *(yyyy-mm-dd)*	End date *(yyyy-mm-dd)*
☐ ATG and Cyclosporin	ATG: CSA:	ATG: CSA:	ATG: CSA:
☐ Cyclosporin/Tacrolimus single agent			
☐ Eltrombopag			
☐ Alemtuzumab			
☐ Androgens			
☐ Other:			

Prior treatment for AA (tick all that apply)

Drug name	Dose/schedule	Start date *(yyyy-mm-dd)*	End date *(yyyy-mm-dd)*
☐ ATG and Cyclosporin	ATG: CSA:	ATG: CSA:	ATG: CSA:
☐ Cyclosporin/Tacrolimus single agent			
☐ Eltrombopag			
☐ Alemtuzumab			
☐ Androgens			
☐ Other:			

Paroxysmal nocturnal hemoglobinuria (PNH)

GPI-anchor defect diagnosis

☐ Absent

☐ Present:

PNH clone size (%) at time of diagnosis (tick all that apply):

☐ Granulocytes _____

☐ Monocytes _____

☐ Red blood cells _____

Please continue on the next page

PNH clone size (%) at time of vaccination (tick all that apply):

☐ Granulocytes _____

☐ Monocytes _____

☐ Red blood cells _____

Current treatment for PNH

Anticoagulation ☐ No ☐ Yes

Blood transfusions ☐ No ☐ Yes

Anti-complement therapy ☐ No ☐ Yes (tick all that apply):

Drug name	Dose/schedule	Start date *(yyyy-mm-dd)*	End date *(yyyy-mm-dd)*
☐ Eculizimab/Ravulizumab			
☐ Other C5 inhibitor			
☐ C3 inhibitor			
☐ Factor B inhibitor			
☐ Factor D inhibitor			
☐ C5 inhibitor plus proximal complement inhibitor			
☐ Other: _____			

Other supportive treatments: _____

_____

Concurrent medication: _____

_____

_____

_____

Please continue on the next page

COVID-19 history

Previously confirmed SARS-CoV-2 infection

☐ No
☐ Yes: date of onset of symptoms _____ *(yyyy-mm-dd)*

symptoms: ☐ No symptoms
☐ Unknown
☐ Upper respiratory tract symptoms
☐ Lower respiratory tract symptoms
☐ Loss of smell/taste
☐ Need for oxygen at diagnosis to keep blood oxygen saturation ≥92%
☐ Other: _____
☐ Pulmonary radiological findings (describe type of radiology and pulmonary pattern):
_____
_____

date of confirmed SARS-CoV-2 infection: _____ *(yyyy-mm-dd)*

confirmation by: ☐ RT-PCR
☐ Antigen test
☐ Serology: ☐ IgG ☐ IgM
IF serology positive:
☐ Anti-spike glycoprotein (anti-S)
☐ Anti-nuclear capsid phosphoprotein (anti-N)
☐ Not known

did the patient receive convalescent plasma?
☐ No ☐ Yes: _____ *(yyyy-mm-dd)*

Disease status of aplastic anaemia <u>before</u> SARS-CoV-2 infection:

☐ Complete remission
☐ Partial remission
☐ Relapse
☐ Progression
☐ Refractory disease
☐ Stable disease (no change, no response)
☐ Not applicable
☐ Not available

Disease status of aplastic anaemia <u>at</u> SARS-CoV-2 infection:

☐ Complete remission
☐ Partial remission
☐ Relapse
☐ Progression
☐ Refractory disease
☐ Stable disease (no change, no response)
☐ Not applicable
☐ Not available

Please continue on the next page

COVID-19 vaccination

COVID-19 vaccination received

☐ No, reason:
- ☐ Patient declined
- ☐ Physician decision due to current disease status
- ☐ Not yet available
- ☐ Other: _____

☐ Yes: date of 1st vaccination: _____ *(yyyy-mm-dd)*

type of vaccination:
- ☐ Pfizer/BioNTech COVID-19 mRNA Vaccine BNT162b2
- ☐ AstraZeneca/Oxford COVID-19 AZD1222
- ☐ Moderna COVID-19 Vaccine (mRNA-1273)
- ☐ Gamaleya Research Institute Sputnik V
- ☐ J&J JNJ-78436735
- ☐ CureVac CVnCoV mRNA Vaccine
- ☐ Other: _____
  _____

date of 2nd vaccination *(if applicable)*: _____ *(yyyy-mm-dd)*

type of vaccination:
- ☐ Pfizer/BioNTech COVID-19 mRNA Vaccine BNT162b2
- ☐ AstraZeneca/Oxford COVID-19 AZD1222
- ☐ Moderna COVID-19 Vaccine (mRNA-1273)
- ☐ Sputnik V by Gamaleya Research Institute
- ☐ J&J JNJ-78436735
- ☐ CureVac CVnCoV mRNA Vaccine
- ☐ Other: _____
  _____

date of 3rd vaccination *(if applicable)*: _____ *(yyyy-mm-dd)*

type of vaccination:
- ☐ Pfizer/BioNTech COVID-19 mRNA Vaccine BNT162b2
- ☐ AstraZeneca/Oxford COVID-19 AZD1222
- ☐ Moderna COVID-19 Vaccine (mRNA-1273)
- ☐ Sputnik V by Gamaleya Research Institute
- ☐ J&J JNJ-78436735
- ☐ CureVac CVnCoV mRNA Vaccine
- ☐ Other: _____
  _____

Disease status of aplastic anaemia before COVID-19 vaccination:

- ☐ Complete remission
- ☐ Partial remission
- ☐ Relapse
- ☐ Progression
- ☐ Refractory disease
- ☐ Stable disease (no change, no response)
- ☐ Not applicable
- ☐ Not available

Please continue on the next page

Blood counts at time of administration of vaccine date _____ (yyyy-mm-dd)

☐ Hb (g/l) _____ *if PNH:*
☐ WCC (x $10E^9$/l) _____ ☐ LDH (IU/L) _____
☐ Neutrophils (x $10E^9$/l) _____ ☐ ULN LDH (IU/L) _____
☐ Platelets (x $10E^9$/l) _____

Complications within 5 days of vaccination

☐ No
☐ Yes: admission required after vaccination: ☐ Yes ☐ No

Side effects (tick all that apply)

☐ Pyrexia
☐ Headache
☐ Fatigue
☐ Haematoma
☐ Myalgia
☐ Other: _____

PNH complications (tick all that apply)

Complications	Site	Date *(yyyy-mm-dd)*
☐ Abdominal pain		
☐ Haemoglobinuria		
☐ Thrombosis		
☐ Other: _____ _____ _____	_____ _____ _____	_____ _____ _____

Management of PNH complications (tick all that apply)

☐ Additional dose of complement inhibition
☐ Observation
☐ Other: _____

Please continue on the next page

Patient status

Status after COVID-19 vaccination

	Date of follow-up *(yyyy-mm-dd)*	Status
3-month follow-up		☐ Alive ☐ Dead
6-month follow-up		☐ Alive ☐ Dead
12-month follow-up		☐ Alive ☐ Dead

Antibody response after COVID-19 vaccination

Important: for vaccines that target the S protein, the serology response should be measured with a test that detects anti-S antibodies. The same applies to the N protein.

Serology testing used by local laboratory:
☐ Anti-S
☐ Anti-N
☐ Not known

	Date Ab response test *(yyyy-mm-dd)*	Status
3-month follow-up		☐ Response achieved* ☐ No response ☐ Not tested
6-month follow-up		☐ Response achieved* ☐ No response ☐ Not tested
12-month follow-up		☐ Response achieved* ☐ No response ☐ Not tested

**Response achieved = antibody positivity*

Please continue on the next page

Blood counts after COVID-19 vaccination *(if unknown/no result/not done please tick 'not done')*

date (yyyy-mm-dd)	3-month follow-up _____	6-month follow-up _____	12-month follow-up _____
Hb (g/l)	_____ ☐ not done	_____ ☐ not done	_____ ☐ not done
WCC (x $10E^9$/l)	_____ ☐ not done	_____ ☐ not done	_____ ☐ not done
Neutrophils (x $10E^9$/l)	_____ ☐ not done	_____ ☐ not done	_____ ☐ not done
Platelets (x $10E^9$/l)	_____ ☐ not done	_____ ☐ not done	_____ ☐ not done

SARS-CoV-2 infection post-vaccination

SARS-CoV-2 infection post-vaccination

☐ No

☐ Yes: date of onset of symptoms _____ *(yyyy-mm-dd)*

symptoms: ☐ No symptoms
☐ Unknown
☐ Upper respiratory tract symptoms
☐ Lower respiratory tract symptoms
☐ Loss of smell/taste
☐ Need for oxygen at diagnosis to keep blood oxygen saturation ≥92%
☐ Other: _____
☐ Pulmonary radiological findings (describe type of radiology and pulmonary pattern):
_____
_____

date of confirmed SARS-CoV-2 infection: _____ *(yyyy-mm-dd)*

confirmation by: ☐ RT-PCR
☐ Antigen test
☐ Serology: ☐ IgG ☐ IgM
IF serology positive:
☐ Anti-spike glycoprotein (anti-S)
☐ Anti-nuclear capsid phosphoprotein (anti-N)
☐ Not known

did the patient receive convalescent plasma?
☐ No ☐ Yes: _____ *(yyyy-mm-dd)*

Please continue on the next page

Disease status after COVID-19 vaccination

3-month follow-up	6-month follow-up	12-month follow-up
☐ Complete remission	☐ Complete remission	☐ Complete remission
☐ Partial remission	☐ Partial remission	☐ Partial remission
☐ Relapse*	☐ Relapse*	☐ Relapse*
☐ Progression	☐ Progression	☐ Progression
☐ Refractory disease	☐ Refractory disease	☐ Refractory disease
☐ Not available	☐ Not available	☐ Not available

*In case of relapse:

Date of first relapse _____ *(yyyy-mm-dd)*

Relapse considered related to:

☐ SARS-CoV-2 infection

☐ Wean of immunosuppression

☐ Other: _____

If patient deceased:

Cause of death (tick all that apply)

☐ COVID-19

☐ Relapse or progression

☐ HSCT-related cause *(check as many as appropriate)*:

	Yes	No	Unknown
GvHD	☐	☐	☐
Interstitial pneumonitis	☐	☐	☐
Pulmonary toxicity	☐	☐	☐
Infection: ☐ bacterial ☐ viral ☐ fungal ☐ parasitic ☐ unknown Site of infection, specify	☐	☐	☐
Rejection / poor graft function	☐	☐	☐
Veno-Occlusive disease (VOD)	☐	☐	☐
Haemorrhage	☐	☐	☐
Cardiac toxicity	☐	☐	☐
Central nervous system toxicity	☐	☐	☐
Gastrointestinal toxicity	☐	☐	☐
Skin toxicity	☐	☐	☐
Renal failure	☐	☐	☐
Multiple organ failure	☐	☐	☐

☐ Unknown

☐ Other : .....

.....

..... *describe all attributable causes of death*

Please continue on the next page

Comments

_____

_____

_____

_____

_____

_____

Thank you!!!

Please send the completed form to:
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