Screening for Eligibility

Subject number _____

eCRF v. 1.0 - Protocol v. 2.3 - 27-04-2020

INFORMED CONSENT

Has informed consent been obtained (verbal or written)? ◯ Yes ◯ No

DO NOT PROCEED IF INFORMED CONSENT HAS NOT BEEN OBTAINED

Date verbal informed consent obtained _____

Has signed informed consent been obtained? ◯ Yes ◯ No

Date signed informed consent obtained _____

If No, give reason _____

SUBJECT ELIGIBILITY

Have all inclusion criteria been met and are none of the exclusion criteria met? ◯ Yes ◯ No
(DO NOT ENROLL PATIENT IF ALL ELIGIBILITY CRITERIA HAVE NOT BEEN MET)

Indicate which inclusion criteria were NOT MET:

☐ Subject (≥18 years old) or legally authorized representative provides informed consent prior to initiation of any study procedures. When signed informed consent is not possible (e.g. due to restrictions to prevent viral transmission), verbal informed consent in the presence of a witness will be obtained and documented in the medical files. Signed informed consent will be obtained as soon as the safety concerns are mitigated.
☐ Subject (or legally authorized representative) understands and agrees to comply with planned study procedures.
☐ Male or non-pregnant female adult ≥18 years of age at time of enrolment.
☐ Patient should be hospitalized
☐ Has a confirmed diagnosis of SARS-CoV-2 infection, defined as either a) lab laboratory-confirmed SARS-CoV-2 infection as determined by PCR, or other commercial or public health assay in any specimen as diagnosed within 60 hours prior to randomization or b) the combination of upper or lower respiratory infection symptoms (fever, cough, dyspnea, desaturation) and typical findings on chest CT scan and absence of other plausible diagnoses
☐ Illness of any duration, and at least one of the following: a) Radiographic infiltrates by imaging (chest x-ray, CT scan, etc.), OR b) Clinical assessment (evidence of rales/crackles on exam) AND SpO2 ≤ 94% on room air OR c) Requiring mechanical ventilation and/or supplemental oxygen.
☐ ABO D typing of the patient should be done at least once and the result should be known.

Indicate which exclusion criteria WERE MET:

- ☐ Receiving invasive (any mode where a patient has been intubated endotracheally, or via tracheostomy) or non-invasive (for instance, but not restricted to CPAP, PSV, PCM, SiMV) mechanical ventilation before or upon randomization
- ☐ Pregnancy or breast feeding
- ☐ Any medical condition which would impose an unacceptable safety hazard by participation to the study
- ☐ Patients with a documented grade 3 allergic reaction after the administration of fresh frozen plasma (i.e. systemic reaction with cardiovascular and/or respiratory involvement)
- ☐ Patients that have treatment restriction that excludes mechanical ventilation and/or endotracheal intubation

SCREEN FAILURE

Did the subject fail screening for any reason other than not meeting eligibility criteria?

◯ Yes ◯ No

Main reason for screen failure

- ◯ Physician decision
- ◯ Subject decision (withdrawal)
- ◯ Death
- ◯ Lost contact with subject
- ◯ Technical concerns
- ◯ Logistical concerns / lack of manpower
- ◯ Needed mechanical ventilation before plasma infusion
- ◯ No compatible convalescent plasma
- ◯ Other reason

Date of death

_____

If reason for screen failure is "Other reason", please specify:

_____

DEMOGRAPHICS

Date of admission

_____

What is the participant's age

_____
(years (must be > or = to 18))

Age range

- ◯ 18-19
- ◯ 20-29
- ◯ 30-39
- ◯ 40-49
- ◯ 50-59
- ◯ 60-69
- ◯ 70-79
- ◯ 80-89
- ◯ 90-99
- ◯ 100-109

(e.g. 30-39, 40-49, etc.)

Participant's gender

- ◯ Female
- ◯ Male
- ◯ Undifferentiated
- ◯ Unknown

What is the participant's ethnicity?	◯ 1. Causasian ◯ 2. North African ◯ 3. Middle east ◯ 4. Black or sub-sahara (africa) ◯ 5. Asian ◯ 6. Latino or hispanic ◯ 7. Pacific islands ◯ 8. Native american or Alaska native
Is the participant pregnant?	◯ Yes ◯ No ◯ Unknown
Body weight	_____ (kg.)

MEDICAL HISTORY

History of diabetes	◯ Yes ◯ No ◯ Unknown
Is the participant insulin-dependent	◯ Yes ◯ No
History of arterial hypertension	◯ Yes ◯ No ◯ Unknown
History of arrhythmia	◯ Yes ◯ No ◯ Unknown
Smoking	◯ Active ◯ Former ◯ Never
Chronic pulmonary disease (not asthma or COPD)	◯ Yes ◯ No ◯ Unknown
If Chronic pulmonary disease, please specify:	_____
COPD	◯ Yes ◯ No ◯ Unknown
Asthma	◯ Yes ◯ No ◯ Unknown
heart failure	◯ Yes ◯ No ◯ Unknown
Ischemic heart disease	◯ Yes ◯ No ◯ Unknown
Moderate or severe liver disease	◯ Yes ◯ No ◯ Unknown
mild liver disease	◯ Yes ◯ No ◯ Unknown
Chronic kidney disease	◯ Yes ◯ No ◯ Unknown
Please specify last known eGRF:	_____
Does the participant require dialysis for chronic kidney disease?	◯ Yes ◯ No

Active cancer	◯ Yes ◯ No ◯ Unknown
Please specify which type of cancer:	_____
History of cancer	◯ Yes ◯ No ◯ Unknown
Please specify type of cancer	_____
Chronic hematologic disease	◯ Yes ◯ No ◯ Unknown
Chronic neurologic disorder	◯ Yes ◯ No ◯ Unknown
HIV/Aids	◯ Yes ◯ No ◯ Unknown
Other relevant chronic diseases	◯ Yes ◯ No ◯ Unknown
Specify which other relevant chronic disease	_____

MAINTENANCE MEDICATION

Is the participant treated with antihypertensive drugs	◯ yes ◯ no ◯ Unknown
Please specify which antihypertensive drugs	☐ ACE inhibitor ☐ Angiotensin receptor blocker ☐ Other
Please specify which 'other' antihypertensive drugs	_____
Please specify which 'other' antihypertensive drugs 2 (if applicable)	_____
Antiplatelet agent	◯ Yes ◯ No ◯ Unknown
Anticoagulation	◯ Yes ◯ No ◯ Unknown
Statines	◯ Yes ◯ No ◯ Unknown
Oral Antidiabetics	◯ Yes ◯ No ◯ Unknown
Insulin	◯ Yes ◯ No ◯ Unknown
Chronic systemic corticosteroid therapy	◯ Yes ◯ No ◯ Unknown
Other immune-suppressing therapy	◯ Yes ◯ No ◯ Unknown
Please specify which other immune-suppressing therapy	_____

Antibiotics	◯ Yes ◯ No ◯ Unknown
Please specify : antibiotic 1	_____
Please specify: antibiotic 2 (if applicable)	_____

THROMBOEMBOLIC EVENT

Was the patient diagnosed with a thrombeombolic event at the baseline visit	◯ Yes ◯ No
Specify which thromboembolic event	_____

EQ-5D-5L questionnaire

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EQ-5D-5L questionnaire completed? ◯ Yes ◯ No

Completion date _____

Indicate why questionnaire was not completed
☐ patient's condiction
☐ logistical reasons
☐ other

specify other _____

EQ-5D-5L questionnaire

MOBILITY
◯ I have no problems in walking about
◯ I have slight problems in walking about
◯ I have moderate problems in walking about
◯ I have severe problems in walking about
◯ I am unable to walk about

SELF-CARE
◯ I have no problems washing or pressing myself
◯ I have slight problems washing or pressing myself
◯ I have moderate problems washing or pressing myself
◯ I have severe problems washing or pressing myself
◯ I am unable to wash or dress myself

USUAL ACTIVITIES
◯ I have no problems doing my usual activities
◯ I have slight problems doing my usual activities
◯ I have moderate problems doing my usual activities
◯ I have severe problems doing my usual activities
◯ I am unable to do my usual activities
(e.g. work, study, housework, family or leisure activities)

PAIN/DISCOMFORT
◯ I have no pain or discomfort
◯ I have slight pain or discomfort
◯ I have moderate pain or discomfort
◯ I have severe pain or discomfort
◯ I have extreme pain or discomfort

ANXIETY/DEPRESSION
◯ I am not anxious or depressed
◯ I am slightly anxious or depressed
◯ I am moderately anxious or depressed
◯ I am severely anxious or depressedd
◯ I am extremely anxious or depressed

We would like to know how good or bad your health is today.
This scale is numbered from 0 to 100.
100 means the best health you can imagine.
0 means the worst health you can imagine.

Mark an X on the scale to indicate how your health is TODAY

0 Your Health TODAY 100

(Place a mark on the scale above)

Please write the number you marked on the scale _____

Baseline

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BASELINE (before administration of plasma)

Date baseline visit	_____
Onset date of first/earliest symptoms	_____
Highest temperature measured at admission	_____

VITAL SIGNS AT BASELINE

Systolic blood pressure on first evalution (mmHg)	_____
Diastolic blood pressure on first evaluation (mmHg)	_____
Oxygen saturation at first presentation	_____ (%)
Lowest measured oxygen saturation when breathing room air	_____ (%)
Does the participant need Oxygen therapy?	◯ No ◯ Flow (L/min) ◯ FiO2 (%)
Provide value for Oxygen flow (L/min)	_____ (% L/min)
Signs of respiratory distress at first presentation (i.e. Sat< 93% OR pO2/FiO2 < 300 OR RR >3 0/min)	◯ Yes ◯ No ◯ Unknown
Consciousness level	◯ Alert ◯ Verbal ◯ Pain ◯ Unresponsive
Hospitalization status	◯ Ward ◯ Intensive care unit ◯ ER

CHRONIC RESPIRATORY SUPPORT AT HOME

Did the patient receive chronic respiratory support at home?	◯ yes ◯ no ◯ unknown
Specify	◯ Oxygen support ◯ Non-invasive ventilation (BIPAP/CIPAP)

MEDICATION

Specific treatment for COVID-19 used	◯ Yes ◯ No
Indicate which specific treatment (s) for COVID-19 is used	☐ Chloroquine ☐ Hydroxychloroquine ☐ Favipiravir ☐ Remdesivir ☐ Tocilizumab ☐ Lopinavir/Ritonavir ☐ Other
Which specific other treatment(s) for COVID-19 is used	_____
Other antiviral drugs used	◯ Yes ◯ No
Indicate which other antiviral drugs is used	_____
Indicate which other antiviral drugs is used (if applicable)	_____
Antibiotics used at admission	◯ Yes ◯ No
Antibiotic 1	_____
Antibiotic 2 (if applicable)	_____
Antibiotic 3 (if applicable)	_____
Antifungal treatment used	◯ Yes ◯ No
Indicate which antifungal treatment used	_____
Indicate which antifungal treatment used (if applicable)	_____

Randomisation

Randomization The randomization button will appear after all necessary fields have been completed.

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FIRST ABO D TYPING

Date and time first ABO D typing	_____
Indicate blood type	◯ A ◯ B ◯ AB ◯ O
Re-enter blood type of first blood sample for confirmation	◯ A ◯ B ◯ AB ◯ O
Indicate Rhesus factor	◯ positive ◯ negative
Re-enter Rhesus factor of first blood sample for confirmation	◯ positive ◯ negative
Is second ABO D typing performed?	◯ Yes ◯ No
Date and time second ABO D typing	_____
Blood type second ABO D typing	◯ A ◯ B ◯ AB ◯ 0
Rhesus factor second ABO D typing	◯ positive ◯ negative

AVAILABILITY COMPATIBLE CONVALESCENT PLASMA!

Is sufficiant compatible convalescent plasma available to be delivered to the hospital for bloodtype [ran_bloodtype], rhesus factor [ran_rf1]	◯ Yes ◯ No
Email(Work variable, used for sending randomization confirmation)	_____
Site (Work variable, used for sending randomization confirmation)	_____
Name of randomizing person	_____
DAWN-PLASMA randomization	
Date and time of Randomization	_____

After randomization: Please, don't forget to set the Form Status to 'COMPLETED' before saving this page. A confirmation email and RED CROSS email is sent only after the page Form Status is set to 'Complete'.

To randomize, click the 'randomize' button

Studyarm	◯ SOC+PLASMA ◯ SOC

Second ABO D Typing

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SECOND ABO D TYPING

Date and time second ABO D typing	_____
Blood type second ABO D typing	◯ A ◯ B ◯ AB ◯ 0
Rhesus factor second ABO D typing	◯ positive ◯ negative

ECG monitoring

eCRF version 1.0 - Protocol version 2.2 - 24-04-2020

ECG performed?	◯ Yes ◯ No
QTc value (ms) (Fredericia formule : QTc = QT interval / (RR interval)1/3) calculator	_____ (ms)

1st Transfusion Plasma

eCRF v. 1.0 - Protocol v. 2.3 - 27-04-2020

Plasma treatment arm	◯ Yes ◯ No

ADMINISTRATION OF BLOOD PRODUCT WITHIN 12 HRS AFTER RANDOMIZATION

First transfusion of convalescent plasma given?	◯ Yes ◯ No
Give reason	_____
Date and time first transfusion of convalescent plama	_____
Number of transfused units	_____
Volume of transfused units	_____
Duration of transfusion	_____
Anti-body titre of transfused units	_____
Did transfusion related side effects occur?	◯ Yes ◯ No (e.g. acute lung injury, serious allergic transfusion reactions, transfusion associated circulatory overload.)
Please specify	☐ Acute lung injury ☐ Serious allergic transfusion reactions ☐ Transfusion associated circulatory overload ☐ Other
Specify other	_____

If this is considered an Adverse Event Grade 4, please complete the Adverse Events page [adverse_event_arm_1][form-link:adverse_events: Link to all patient adverse_events (first record)] - Total number of records: [adverse_event_arm_1][ae_total][last-instance]

2nd Transfusion Plasma

eCRF v. 1.0 - Protocol v. 2.3 - 27-04-2020

Plasma treatment arm ◯ Yes ◯ No

ADMINISTRATION OF BLOOD PRODUCT 24-36 HRS AFTER FIRST ADMINISTRATION

Second transfusion of convalescent plasma given? ◯ Yes ◯ No

Give reason

_____

Date and time second transfusion of convalescent plama

_____

Number of transfused units

_____

Volume of transfused units

_____

Duration of transfusion

_____

Anti-body titre of transfused units

_____

Did transfusion related side effects occur? ◯ Yes ◯ No
(e.g. acute lung injury, serious allergic transfusion reactions, transfusion associated circulatory overload.)

Please specify
☐ Acute lung injury
☐ Serious allergic transfusion reactions
☐ Transfusion associated circulatory overload
☐ Other

Specify other

_____

If this is considered an Adverse Event Grade 4, please complete the Adverse Events page [adverse_event_arm_1][form-link:adverse_events: Link to all patient adverse_events (first record)] - Total number of records: [adverse_event_arm_1][ae_total][last-instance]

Clinical Status

eCRF v. 1.0 - Protocol v. 2.3 - 27-04-2020

CLINICAL STATUS

Clinical status recorded on	_____
Clinical status	◯ Uninfected.Non viral RNA detected ◯ Ambulatory, Asymptomatic, viral RNA detected ◯ Ambulatory, Symptomatic, Independent ◯ Ambulatory, Symptomatic, Assistance needed ◯ Hospitalized, mild disease, No oxygen therapy needed ◯ Hospitalized, mild disease, Oxygen by mask or nasal prongs ◯ Hospitalized, severe disease, Oxygen by NIV or High flow ◯ Hospitalized, severe disease, Intubation and mechanical ventilation (pO2/FiO2>=150 OR SpO2/FiO2>=200) ◯ Hospitalized, severe disease, Mechanical ventilation (pO2/FiO2< 150 OR SpO2/FiO2< 200) OR vasopressors (norepinephrine > 0.3microg/kg/min) ◯ Hospitalized, severe disease, Mechanical ventilation (pO2/FiO2< 150 AND vasopressors (norepinephrine > 0.3microg/kg/min), OR Dialysis OR ECMO ◯ Death, Dead
Oxygen support at home?	◯ Yes ◯ No
Hospitalization status at 08:00 am	◯ Ward ◯ Intensive Care Unit
SOFA-score (enter a number from 0-24	_____ (Enter a number from 0 to 24)
APACHE-II score	_____ (Enter a number from 0 to 71)
Cause of death	◯ respiratory failure ◯ multiorgan failure ◯ heart failure ◯ sudden unexpected or arrhythmic death
Amount of oxygen given (FiO2)	_____ (Complete this field for the first 14 days of admission)
Highest body temperature measured	_____ (°c)

Visit

eCRF v. 1.0 - Protocol v. 2.3 - 27-04-2020

VISIT (complete daily until discharge)

Visit performed	◯ Yes ◯ No
Visit date	_____
If visit was not done, please provide reason	◯ Subject is lost to follow up ◯ Subject withdrew consent ◯ Subject died ◯ Other ◯ Subject left the hospital (dismissed)
Date of discharge	_____
Specify "Other" reason why visit was not done	_____
Was the patient in ICU for the past 24 hours ?	◯ Yes ◯ No
Signs of respiratory distress (i.e. Sat < 93% OR pO2/FiO2 < 300 or RR > 30/min)	◯ Yes ◯ No ◯ Unknown

Support

Is the patient currently receiving, or has received (between 00:00 to 24:00 on the day of assessment) (apply to all questions in this section):

Oxygen support	◯ Yes ◯ No ◯ Unknown
High flow oxygen support(e.g. optiflow)	◯ Yes ◯ No ◯ Unknown
Non invasive ventilation (e.g. BIPAP, CPAP)	◯ Yes ◯ No ◯ Unknown
Invasive ventilation	◯ Yes ◯ No ◯ Unknown
Prone ventilation	◯ Yes ◯ No ◯ Unknown
Extra corporeal life support(ECMO)	◯ Yes ◯ No ◯ Unknown
Inhaled nitric oxide	◯ Yes ◯ No ◯ Unknown
Dialysis/Hemofiltration	◯ Yes ◯ No ◯ Unknown
Specific treatment used other than plasma	◯ Yes ◯ No

Specify treatments	☐ Chloroquine ☐ Hydroxychloroquine ☐ Favipiravir ☐ Remdesivir ☐ Tocilizumab ☐ Lopinavir/Ritonavir ☐ Other
Specify 'Other'	_____
Other antiviral drugs used	◯ Yes ◯ No
Specifiy other antiviral drug 1	_____
Specify other antiviral drug 2 (if applicable)	_____
Antibiotics used	◯ Yes ◯ No
Specifiy antibiotics 1	_____
Specify antibiotics 2 (if applicable)	_____
Antifungal treatment used	◯ Yes ◯ No
Specify antifungal treatment 1	_____
Specify antifungal treatment 2 (if applicable)	_____
Is the patient receiving ACE-inbitors or Angiotensine Receptor-Blockers?	◯ Yes ◯ No
Specify	_____
Is the patient receiving NSAID?	◯ Yes ◯ No
Specify NSAID 1	_____
Specify NSAID 2 (if applicable)	_____
Is the patient receiving systemic corticosteroids?	◯ Yes ◯ No
Specify	_____

SERIOUS ADVERSE EVENTS AND ADVERSE EVENTS GRADED AS SEVERE

Did new adverse events occur since previous visit, or have there been changes in previously reported conditions?	◯ Yes ◯ No
Was Adverse Events page completed?	◯ Yes ◯ No ◯ Not applicable (non-reportable event)

Please complete Adverse Events page [adverse_event_arm_1][form-link:adverse_events: Link to all patient adverse_events (first record)] - Total number of records: [adverse_event_arm_1][ae_total][last-instance]

Visit D15

eCRF v. 1.0 - Protocol v. 2.3 - 27-04-2020

VISIT D15

Visit performed (either by phone or in hospital)	◯ Yes ◯ No
Patient still hospitalized	◯ Yes ◯ No
Visit date	_____
If visit was not done, please provide reason	◯ Subject is lost to follow up ◯ Subject withdrew consent ◯ Subject died ◯ Other ◯ Subject left the hospital (dismissed)
Date of death	_____
Date of discharge	_____
If "Other" reason, please explain	_____
Was the patient readmitted in the hospital after discharge?	◯ Yes ◯ No
Date of readmission	_____
Was the patient readmitted due to COVID-19?	◯ Yes ◯ No
If not, what was the reason for hospitalisation?	_____

SUPPORT

Is the patient currently receiving, or has received (between 00:00 to 24:00 on the day of assessment) (apply to all questions in this section):

Oxygen support	◯ Yes ◯ No ◯ Unknown
High flow oxygen support(e.g. optiflow)	◯ Yes ◯ No ◯ Unknown
Non invasive ventilation (e.g. BIPAP, CPAP)	◯ Yes ◯ No ◯ Unknown
Invasive ventilation	◯ Yes ◯ No ◯ Unknown

Prone ventilation	◯ Yes ◯ No ◯ Unknown
Extra corporeal life support(ECMO)	◯ Yes ◯ No ◯ Unknown
Inhaled nitric oxide	◯ Yes ◯ No ◯ Unknown
Dialysis/Hemofiltration	◯ Yes ◯ No ◯ Unknown

SYMPTOMS

Signs of respiratory distress (i.e. Sat < 93% OR pO2/FiO2 < 300 or RR > 30/min)	◯ Yes ◯ No ◯ Unknown
Select symptoms that occured during last 24 hours	☐ Fever ☐ Sore throat ☐ Runny nose ☐ Shortness of breath ☐ Cough ☐ Wheezing ☐ Chest pain ☐ Muscle aches (Myalgia) ☐ Joint pain (Arthralagia) ☐ Fatigue/Malaise ☐ Headache ☐ Altered conciousness/confusion ☐ Seizures ☐ Abdominal pain ☐ Nausea ☐ Decreased apitite ☐ Vomiting ☐ Diarrhea ☐ Conjunctivitis ☐ Skin rash ☐ Skin ulcers ☐ Lymphadenopathy ☐ Sleep disorders and disturbances ☐ Bleeding(Haemorrhage)

SERIOUS ADVERSE EVENTS AND ADVERSE EVENTS GRADED AS SEVERE
(i.e. AE that are life-threatening and/or require an urgent intervention)

Did new adverse events occur since previous visit, or have there been changes in previously reported conditions?	◯ Yes ◯ No
Was Adverse Events page completed?	◯ Yes ◯ No ◯ Not applicable (non-reportable event)

Please complete Adverse Events page [adverse_event_arm_1][form-link:adverse_events: Link to all patient adverse_events (first record)] - Total number of records: [adverse_event_arm_1][ae_total][last-instance]

Visit D30

eCRF v. 1.0 - Protocol v. 2.3 - 27-04-2020

VISIT D30

Visit performed (either by phone or in hospital)	◯ Yes ◯ No
Patient still hospitalized	◯ Yes ◯ No
Visit date	_____
If visit was not done, please provide reason	◯ Subject is lost to follow up ◯ Subject withdrew consent ◯ Subject died ◯ Other ◯ Subject left the hospital (dismissed)
Date of death	_____
Date of discharge	_____
Specify "Other" reason why visit was not done	_____
Was the patient readmitted in the hospital after discharge?	◯ Yes ◯ No
Date of readmission	_____
Was the patient readmitted due to COVID-19?	◯ Yes ◯ No
If not, what was the reason for hospitalisation?	_____

SUPPORT

Is the patient currently receiving, or has received (between 00:00 to 24:00 on the day of assessment) (apply to all questions in this section):

Oxygen support	◯ Yes ◯ No ◯ Unknown
High flow oxygen support(e.g. optiflow)	◯ Yes ◯ No ◯ Unknown
Non invasive ventilation (e.g. BIPAP, CPAP)	◯ Yes ◯ No ◯ Unknown
Invasive ventilation	◯ Yes ◯ No ◯ Unknown

Prone ventilation	◯ Yes ◯ No ◯ Unknown
Extra corporeal life support(ECMO)	◯ Yes ◯ No ◯ Unknown
Inhaled nitric oxide	◯ Yes ◯ No ◯ Unknown
Dialysis/Hemofiltration	◯ Yes ◯ No ◯ Unknown

SYMPTOMS

Signs of respiratory distress ◯ Yes ◯ No ◯ Unknown

(i.e. Sat < 93% OR pO2/FiO2 < 300 or RR > 30/min)

Select symptoms that occured during last 24 hours

- ☐ Fever
- ☐ Sore throat
- ☐ Runny nose
- ☐ Shortness of breath
- ☐ Cough
- ☐ Wheezing
- ☐ Chest pain
- ☐ Muscle aches (Myalgia)
- ☐ Joint pain (Arthralagia)
- ☐ Fatigue/Malaise
- ☐ Headache
- ☐ Altered conciousness/confusion
- ☐ Seizures
- ☐ Abdominal pain
- ☐ Nausea
- ☐ Decreased apitite
- ☐ Vomiting
- ☐ Diarrhea
- ☐ Conjunctivitis
- ☐ Skin rash
- ☐ Skin ulcers
- ☐ Lymphadenopathy
- ☐ Sleep disorders and disturbances
- ☐ Bleeding(Haemorrhage)

SERIOUS ADVERSE EVENTS AND ADVERSE EVENTS GRADED AS SEVERE
(i.e. AE that are life-threatening and/or require an urgent intervention)

Did new adverse events occur since previous visit, or have there been changes in previously reported conditions? ◯ Yes ◯ No

Was Adverse Events page completed? ◯ Yes ◯ No ◯ Not applicable (non-reportable event)

Please complete Adverse Events page [adverse_event_arm_1][form-link:adverse_events: Link to all patient adverse_events (first record)] - Total number of records: [adverse_event_arm_1][ae_total][last-instance]

Visit D90

eCRF v. 1.0 - Protocol v. 2.3 - 27-04-2020

VISIT D90

Visit performed (either by phone or in hospital)	◯ Yes ◯ No
Patient still hospitalized	◯ Yes ◯ No
Visit date	_____
If visit was not done, please provide reason	◯ Subject is lost to follow up ◯ Subject withdrew consent ◯ Subject died ◯ Other ◯ Subject left the hospital (dismissed)
Date of death	_____
Date of discharge	_____
Specify "Other" reason why visit was not done	_____
Was the patient readmitted in the hospital after discharge?	◯ Yes ◯ No
Date of readmission	_____
Was the patient readmitted due to COVID-19?	◯ Yes ◯ No
If not, what was the reason for hospitalisation?	_____

SUPPORT

Is the patient currently receiving, or has received (between 00:00 to 24:00 on the day of assessment) (apply to all questions in this section):

Oxygen support	◯ Yes ◯ No ◯ Unknown
High flow oxygen support(e.g. optiflow)	◯ Yes ◯ No ◯ Unknown
Non invasive ventilation (e.g. BIPAP, CPAP)	◯ Yes ◯ No ◯ Unknown
Invasive ventilation	◯ Yes ◯ No ◯ Unknown

Prone ventilation	◯ Yes ◯ No ◯ Unknown
Extra corporeal life support(ECMO)	◯ Yes ◯ No ◯ Unknown
Inhaled nitric oxide	◯ Yes ◯ No ◯ Unknown
Dialysis/Hemofiltration	◯ Yes ◯ No ◯ Unknown

SYMPTOMS

Signs of respiratory distress (i.e. Sat < 93% OR pO2/FiO2 < 300 or RR > 30/min)	◯ Yes ◯ No ◯ Unknown
Select symptoms that occured during last 24 hours	☐ Fever ☐ Sore throat ☐ Runny nose ☐ Shortness of breath ☐ Cough ☐ Wheezing ☐ Chest pain ☐ Muscle aches (Myalgia) ☐ Joint pain (Arthralagia) ☐ Fatigue/Malaise ☐ Headache ☐ Altered conciousness/confusion ☐ Seizures ☐ Abdominal pain ☐ Nausea ☐ Decreased apitite ☐ Vomiting ☐ Diarrhea ☐ Conjunctivitis ☐ Skin rash ☐ Skin ulcers ☐ Lymphadenopathy ☐ Sleep disorders and disturbances ☐ Bleeding(Haemorrhage)

SERIOUS ADVERSE EVENTS AND ADVERSE EVENTS GRADED AS SEVERE
(i.e. AE that are life-threatening and/or require an urgent intervention)

Did new adverse events occur since previous visit, or have there been changes in previously reported conditions?	◯ Yes ◯ No
Was Adverse Events page completed?	◯ Yes ◯ No ◯ Not applicable (non-reportable event)

Please complete Adverse Events page [adverse_event_arm_1][form-link:adverse_events: Link to all patient adverse_events (first record)] - Total number of records: [adverse_event_arm_1][ae_total][last-instance]

PLEASE COMPLETE END OF STUDY VISIT.

Please complete End of Study Visit

_____

Lab values

eCRF v. 1.0 - Protocol v. 2.3 - 27-04-2020

Blood sample taken? ◯ Yes ◯ No

Date lab values _____

CRP (mg/L) _____ (mg/L)

White blood cell count (x10^9/L) _____

Absolute lymphocyte count (10*9/L) _____

Absolute neutrophil count (10*9/L) _____

Absolute eosinophil count (10*9/L) _____

Hemoglobin (g/dl) _____

Platelet count (x10^9/L) _____

Serum creatinin (mg/dl) _____

AST (U/L) _____

ALT (U/L) _____

Alkaline phosphatase (U/L) _____

Potassium _____ (mmol/L)

Total Bilirubin _____ (mg/dL)

Troponin T hs (µg/L) _____

LDH	_____ (U/L)
Glucose (mg/dl)	_____
Ferritine (µg/L)	_____
D-dimer (µg/L)	_____
Fibrinogen (g/L)	_____
eGFR (CKD-EPI) (ml/min)	_____

Pathogen Testing

eCRF v. 1.0 - Protocol v. 2.3 - 27-04-2020

PATHOGEN TESTING: SARS-CoV-2- DETECTION
(Enter every sample sent for SARS-CoV-2)

Date of detection

_____

Sample method ◯ NP swap ◯ BAL ◯ Other

Specify which other method

_____

Result ◯ positive ◯ negative

If Yes, specify

☐ COVID
☐ non-COVID virus
☐ bacteria
☐ fungus
☐ other

Specify other 1

_____

Specify other 2 (if applicable)

_____

Specify other 3 (if applicable)

_____

Neutralisation antibody titer

Neutralisation antibody titer	
Sample taken?	◯ Yes ◯ No
NT50	_____
NT90	_____

Adverse Events

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ADVERSE EVENTS
Definition of 'ADVERSE EVENT' (AE): any untoward medical occurrence in a patient administered a pharmaceutical product and which does not necessarily have a causal relation with this treatment.

Any SERIOUS adverse event (SAE) must be reported within 24 hours of awareness.

Definition of 'SERIOUS adverse event':
A serious adverse event (SAE) is any event that results in any of the following:

Results in death Is life-threatening Requires inpatient hospitalisation or prolongation of existing hospitalisation Results in persistent or significant disability or incapacity Is a congenital anomaly or birth defect Is an important medical event

Legend for severity of AE :

Mild: no or transient symptoms, no interference with the subject's daily activities Moderate: marked symptoms, moderate interference with the subject's daily activities Severe: considerable interference with the subject's daily activities, unacceptable For this trial, only AE graded as severe shall be collected, i.e. adverse events that are life-threatening and/or require an urgent intervention.

Total number of pages

_____

Describe Event

_____

MedDRA LLT

_____
(Most recent version of MedDRA dictionary is uploaded automatically during routine system updates)

Start date

_____

Stop date

_____

Outcome	◯ Recovered ◯ Recovered with sequelae ◯ Not yet recovered ◯ Fatal
Action taken	☐ No action taken ☐ Medication ☐ Non-drug therapy ☐ Further investigation performed ☐ Stop study participation due to AE ☐ Other
Ensure to update Concomitant Therapy page [concomitant_medica_arm_1][form-link:concomitant_therapy: Link to all patient Concomitant Medication (first record)] - Total number of records: [concomitant_medica_arm_1][contx_total][last-instance]	
Other	_____
Action taken regarding study treatment	☐ No action taken ☐ Temporarily interrupted ☐ Stopped permanently ☐ Other ☐ N/a (study treatment not started yet)
Other	_____

Investigator's assessment

Seriousness	
Serious AE?	◯ Yes ◯ No
Date of awareness	_____
If yes, tick all criteria that apply:	
	☐ Resulted in death
Date of death	_____
	☐ Is life-threatening
	☐ Results in persistent or significant disability/incapacity
	☐ Requires or prolongs in patient hospitalization
Date of hospitalization	_____

Is hospitalization ongoing?	◯ Yes ◯ No
Date of discharge	_____
	☐ Is a congenital anomaly or birth defect
	☐ Is considered as an important medical event
Severity	
Severity	◯ Mild ◯ Moderate ◯ Severe
Causality to study treatment	
Causality	◯ Not Related ◯ Unlikely ◯ Possibly ◯ Probably ◯ Definitely ◯ Unknown
Expectedness of event	◯ Expected ◯ Unexpected
Causality to study procedure	
Causality to study procedure?	◯ Yes ◯ No ◯ Unknown (Study procedure = a procedure performed specifically for the study, outside the standard of care)
If yes, specify study-specific procedure	_____
Any other comments	_____

Concomitant Therapy

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Total number of pages

_____

IMPORTANT: Please, list all medication / non-drug therapy taken by the subject while participating in the study

Generic medication name / non-drug therapy

_____

Reason for concomitant therapy

◯ Pre-existing condition
◯ Adverse event
◯ Other

Define pre-existing condition

_____

Adverse event description

_____

If "Other" reason for concomitant therapy, please specify

_____

Start date

_____

Stop date

_____

☐ ongoing

Dose

_____

Dose unit

◯ mg
◯ gr
◯ ml
◯ cl
◯ IU
◯ Appl
◯ dr
◯ %
◯ Other

If "Other", please specify unit:

_____

End of Study

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END OF STUDY

Date End of Trial visit	_____
Primary reason for trial participation termination	◯ Subject completed study as per protocol ◯ Physician decision ◯ Subject decision (withdrew consent) ◯ Lost contact with subject ◯ Adverse Event ◯ Death ◯ Protocol violation(s) ◯ Other
Date of death	_____
If "Other" reason for trial participation termination, please specify	_____

OUTCOME

Outcome	◯ Discharged alive ◯ Hospitalization ◯ Transfer to other facility ◯ Death ◯ Palliative discharge ◯ Unknown
Outcome date	_____
Date of discharge	_____
Post-discharged alive	☐ Oxygen therapy ☐ Dialysis/renal treatment ☐ Other intervention/procedure
Specify other intervention/procedure	_____
Specify transfer facility name	_____