Confidential

Demographics And Epidemiological Factors

Record ID	_____
Demographics	
Subject ID	_____
Patient Initial	_____
Date of Birth	_____
Age	_____ (year)
Enrolment date	_____
Ethnic group	◯ Arab ◯ Non Arab
Nationality	_____
Gender	◯ Male ◯ Female
Epidemiological Factors	
1.Close contact* with a confirmed or probable case of COVID-19 infection, while that patient was symptomatic	◯ Yes ◯ No ◯ Unknown
2.Presence in a healthcare facility where COVID-19 infections have been managed	◯ Yes ◯ No ◯ Unknown
3.Presence in a laboratory handling suspected or confirmed COVID-19 samples	◯ Yes ◯ No ◯ Unknown

Confidential

Clinical Inclusion And Exclusion Criteria

Inclusion Criteria		
1.Male or non-pregnant female	◯ Yes	◯ No
2.Diagnosed with Mild COVID-19 by Positive PCR confirmed SARS-coV-2 all the time of recruitment	◯ Yes	◯ No
3.Able to sign the consent form and agree to clinical samples collection (or their legal surrogates if subjects are or become unable to make informed decisions).	◯ Yes	◯ No
4.Patient enrolled within 5 days of disease onset	◯ Yes	◯ No
5.Must agree not to enroll in another study of an investigational agent prior to completion of Day 28 of study.	◯ Yes	◯ No

Exclusion Criteria		
1.Patients with concomitant documented bacterial pneumonia	◯ Yes	◯ No
2. Patients who are pregnant or breastfeeding	◯ Yes	◯ No
3. Known sensitivity/allergy to Favipiravir	◯ Yes	◯ No
4. Major comorbidities increasing the risk of study drug including: i. Hematologic malignancy, ii. Advanced (stage 4-5) chronic kidney disease or dialysis therapy, Severe liver damage (Child-Pugh score ≥ C, AST> 5 times the upper limit), HIV.	◯ Yes	◯ No
5. Gout/history of Gout or hyperuricemia (two times above the ULN)	◯ Yes	◯ No
6.Having used Favipiravir or participated in any other interventional drug clinical study within 30 days prior to first dose of study drug.	◯ Yes	◯ No

Confidential

7.The investigator believes that participating in the trial is not in the best interests of the patient, or the investigator considers unsuitable for enrollment (such as unpredictable risks or subject compliance issues)	◯ Yes ◯ No
8.Clinical prognostic non-survival, palliative care, or in deep coma and have no response to supportive treatment within three hours of admission	◯ Yes ◯ No
Randomization	
Site	◯ Site1 ◯ Site2 ◯ Site3 ◯ Site4 ◯ Site5 ◯ Site6 ◯ Site7 ◯ Site8 ◯ Site9 ◯ Site10
Patient Recruited in ?	◯ Hospital ◯ Community
Treatment	◯ A ◯ B ◯ C ◯ D
Randomization Time	_____

Confidential

Co-Morbidities

Height

_____ (cm)

Weight

_____ (kg)

Co-morbidities and risk factors - Charlson Index will be calculated for each patient at analysis.

	Yes	No	NA
Hypertension	◯	◯	◯
Chronic cardiac disease, including congenital heart disease (not hypertension)	◯	◯	◯
Chronic pulmonary disease (not asthma)	◯	◯	◯
Asthma (physician diagnosed)	◯	◯	◯
Chronic kidney disease	◯	◯	◯
Chronic liver disease	◯	◯	◯
Chronic neurological disorder	◯	◯	◯
Chronic Rheumatologic/Auto-immune disorder	◯	◯	◯
Obesity (BMI more than 30)	◯	◯	◯
Diabetes with complications	◯	◯	◯
Diabetes without complications	◯	◯	◯
Smoking	◯	◯	◯
Other	◯	◯	◯

Specify, Other Co-Morbidities

_____

Confidential

Onset And Admission

At Other Facility	
Onset date of first/earliest symptom	_____
Did the patient visit another health care facility since the onset date of first/earliest symptom?	◯ Yes ◯ No ◯ NA
Date of the visit	_____
Name of Facility	_____
City	_____
What health care was provided?	◯ Inpatient (Ward, ICU) ◯ Outpatient (ER, Clinic, Primary Care) ◯ NA ◯ Others
Was admission required?	◯ Yes ◯ No ◯ NA
Date of Admission	_____
Date of Discharge	_____
At This Facility	
Location of Patient at the Time of Randomization	◯ Outpatient ◯ ER ◯ Ward
Was Admission Required?	◯ Yes ◯ No ◯ NA
Admission Date at this Facility	_____

Confidential

Vital Signs At Randomization

(First Available Data at Presentation/Admission-within 24 Hours)	
Temperature	_____ (°C)
Heart Rate	_____ (Beats Per Minute)
Respiratory Rate	_____ (Breaths Per Minute)
Systolic BP	_____ (mmHg)
Diastolic BP	_____ (mmHg)
Oxygen Saturation:	_____ (%)
Oxygen saturation On:	◯ Room air ◯ Oxygen therapy ◯ NA
Specify Therapy	◯ Nasal Cannula ◯ Facemask ◯ Non- rebreathable mask ◯ High flow nasal cannula ◯ Non-invasive ventilation (BiPap, CPap) ◯ Invasive Mechanical Ventilation
Please, mention amount	_____
	◯ L/min ◯ %

Confidential

Symptoms

Observed/reported at admission and associated with this episode of acute illness			
	Yes	No	NA
Fever	◯	◯	◯
Cough	◯	◯	◯
Cough with Sputum Production	◯	◯	◯
Cough with Bloody Sputum/Haemoptysis	◯	◯	◯
Sore Throat	◯	◯	◯
Runny Nose (Rhinorrhoea)	◯	◯	◯
Chest Pain	◯	◯	◯
Shortness of Breath (Dyspnea)	◯	◯	◯
Loss of smell	◯	◯	◯
Loss of taste	◯	◯	◯
Abdominal Pain	◯	◯	◯
Vomiting / Nausea	◯	◯	◯
Diarrhoea	◯	◯	◯
Ear Pain	◯	◯	◯
Muscle Aches (Myalgia)	◯	◯	◯
Joint Pain (Arthralgia)	◯	◯	◯
Fatigue / Malaise	◯	◯	◯
Lower Chest Wall Indrawing	◯	◯	◯
Headache	◯	◯	◯
Conjunctivitis	◯	◯	◯
Skin Rash	◯	◯	◯
Skin Ulcers	◯	◯	◯
Lymphadenopathy	◯	◯	◯

Confidential

Daily Clinical Assesment

Complete one form on admission, one form on admission to ICU, and daily up to 28 days or until discharge or death if earlier. Record the worst value between 00:00 to 24:00 on day of assessment (if Not Available write 'N/A')

Study Day (clinical assesment study day start on 2nd day after randomization)	_____ (Day)
Date of Phone Assesment	_____
Time	_____
Current admission to ICU?	◯ Yes ◯ No
FiO2 (0.21-1.0)	_____
SaO2	_____ (%)
PaO2 at time of FiO2 above	_____
	◯ kPa ◯ mmHg
PaO2 sample type:	◯ Arterial ◯ Venous ◯ Capillary ◯ N/A
From same blood gas record as PaO2	_____
	◯ kPa ◯ mmHg
pH	_____
HCO3	_____ (mEq/L)

Confidential

Systolic Blood Pressure

_____ (mmHg)

Diastolic Blood Pressure

_____ (mmHg)

Mean Arterial Blood Pressure

_____ (mmHg)

Urine flow rate

_____ (mL/24 hoursCheck if estimated)

Glasgow Coma Score (GCS / 15)

_____

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

	Yes	No	N/A
Non-invasive ventilation (e.g. BIPAP, CPAP)	◯	◯	◯
Invasive ventilation	◯	◯	◯
Extra corporeal life support (ECLS)	◯	◯	◯
High-flow nasal cannula oxygen therapy	◯	◯	◯
Dialysis/Hemofiltration	◯	◯	◯
Any vasopressor/inotropic support	◯	◯	◯

Progress of Symptoms at 1st Presentation(pyrexia, short of breath, and relief of cough and/or others) Can stop recording if resolved for 72 hours

◯ Worsening
◯ Same
◯ Better
◯ Resolved

Signs and Symptoms

New signs and symptoms ◯ Yes ◯ No

Specify,

_____ (L/min)

Starting Date

_____

Fever ◯ Yes, ◯ No

Confidential

Fever Result	_____ (°C)
Any hospital/ER visits	◯ Yes ◯ No
Was Vital Signs Collected?	◯ Yes ◯ No
Temperature	_____ (°C)
Heart Rate	_____ (Beat Per Minut)
Respiratory Rate	_____ (Breath Per Minute)
Systolic Blood Pressure	_____ (mmHg)
Diastolic Blood Pressure	_____ (mmHg)
Oxygen Saturation	_____ (%)
Oxygen On	◯ Room air ◯ Oxygen therapy ◯ NA
Specify, Oxygen Therapy	_____

Confidential

SARS-2-COV Testing

Sample study day	◯ Day 1(-5 day) ◯ Day 5 (+/- 1 day) ◯ Day 10 (+/-1 day) ◯ Day 15 (+/- 2 day)
Collection Date	_____
Biospecimen Type	◯ Nasopharyngeal swab ◯ Oropharyngeal swab ◯ Combined Nasopharyngeal and Oropharyngeal swab ◯ Sputum ◯ BAL
Laboratory labResult	◯ Positive ◯ Negative ◯ NA

Confidential

Lab Assessment Form

Complete one form on admission, one form on admission to ICU, and daily up to 28 days or until discharge or death if earlier. Record the worst value between 00:00 to 24:00 on day of assessment (if Not Available write 'N/A')

Study Day

◯ Day 1 (+1 day)
◯ Day 5 (±1 day)
◯ Day 10 (±1 day)
◯ Day 15 (±2 day)

Laboratory Assessement

Haemoglobin

_____

◯ g/L ◯ g/dL

WBC Count

_____

◯ x109/L ◯ x103/µL

Lymphocyte count

_____
(cells/ µL)

Neutrophil count

_____
(cells/ µL)

Platelets

_____

◯ x109/L ◯ x103/µL

ALT/SGPT

_____
(U/L)

Total Bilirubin

_____

◯ µmol/L ◯ mg/dL

AST/SGOT

_____
(U/L)

Glucose

_____

Confidential

	◯ mmol/L ◯ mg/dL
Blood Urea Nitrogen (urea)	_____
	◯ mmol/L ◯ mg/dL
	◯ mmol/L ◯ mg/dL
Creatinine	_____
	◯ umol/L ◯ mg/dL
Sodium	_____ (mEq/L)
Potassium	_____ (mEq/L)
Chest X-Ray performed?	◯ Yes ◯ No ◯ NA
Were Infiltrates Present?	◯ Yes-Unilateral ◯ Yes - Bilateral ◯ No ◯ NA
.	
ECG performed?	◯ Yes ◯ No ◯ N/A
if YES QT Interval	_____

Confidential

Daily Study Drug

Favipiravir / Placebo	
Was Favipiravir given?	◯ Yes ◯ No
Dose	_____
Dose Number	_____
Date	_____
Time given	_____
Drug Method	◯ Syrup ◯ tablet

Confidential

Pathogen Testing

Was Other pathogen testing done during this illness episode?	◯ Yes ◯ No ◯ NA
Bacteria	◯ Yes - confirmed ◯ No
What Bacteria?	_____
Other Infectious Respiratory Diagnosis	◯ Yes- Confirmed ◯ Yes- Probable ◯ No
Specify, Other Infectious Respiratory Diagnosis	_____
If None of the Above , Suspected Non-Infective	◯ Yes ◯ No

Confidential

Complication (At day 28)

At any time during hospitalization did the patient experience:		
	Yes	No
Pulmonary Embolism	◯	◯
Bacterial Pneumonia	◯	◯
Coagulopathy	◯	◯
Acute lung Injury/ARDS	◯	◯
Anemia	◯	◯
Pneumothorax	◯	◯
Pleural Effusion	◯	◯
Acute renal Injury/Failure	◯	◯
Seizure	◯	◯
Congestive Heart Failure	◯	◯
Meningitis/ Encephalitis	◯	◯
Stroke/Cerebrovascular Accident	◯	◯
Endocarditis / Myocarditis / Pericarditis	◯	◯
Cardiac Arrhythmia	◯	◯
Bacteremia	◯	◯
Cardiac Arrest	◯	◯
Liver Dysfunction	◯	◯
Rhabdomyolysis / Myositis	◯	◯
Other	◯	◯

Specify other Complication _____

Confidential

Treatment

At any time during enrollment did the patient receive/undergo?	
Hospital admission?	◯ YES ◯ NO ◯ N/A
date of hospital admission	_____
date of hospital discharge	_____
ICU or High Dependency Unit Admission?	◯ Yes ◯ No ◯ NA
Date of ICU Admission	_____
Date of ICU Discharge	_____
Oxygen Therapy?	◯ Yes ◯ No ◯ NA
Specify therapy	_____
Non-invasive Ventilation? (e.g. BIPAP, CPAP)	◯ Yes ◯ No ◯ NA
Invasive Ventilation (Any)?	◯ Yes ◯ No ◯ NA
Total Duration	_____ (Days)
Tracheostomy Inserted	◯ Yes ◯ No ◯ NA
ECMO?	◯ Yes ◯ No ◯ NA
Renal Replacement Therapy (RRT) or Dialysis?	◯ Yes ◯ No ◯ NA
Inotropes/Vasopressors?	◯ Yes ◯ No ◯ NA
First/Start Date	_____

Confidential

Last/End Date	_____
OTHER Intervention or Procedure	_____

Confidential

Medication

Antiviral Agent?	◯ Yes ◯ No ◯ NA
Specify, Antiviral Agent	☐ Favipiravir ☐ Hydroxychloroquine ☐ chloroquine ☐ Lopinavir/Ritonavir ☐ Azithromycin ☐ Interferon ☐ Oseltamivir
Favipiravir Dose	_____
Favipiravir_ start date	_____
Favipiravir_ end date	_____
Hydroxychloroquine Dose	_____
Hydroxychloroquine_Start date	_____
Hydroxychloroquine_End date	_____
Chloroquine Dose	_____
Chloroquine _Start date	_____
Chloroquine _End date	_____
Lopinavir/Ritonavir Dose	_____
Lopinavir/Ritonavir_Start Date	_____
Lopinavir/Ritonavir_End Date	_____
Azithromycin Dose	_____
Azithromycin_Start date	_____

Confidential

Azithromycin_end date	_____
Interferon Dose	_____
Interferon_Start date	_____
Interferon_End date	_____
Oseltamivir Dose	_____
Oseltamivir_Start date	_____
Oseltamivir_End date	_____
Anti-Interleukin-6 Agents?	◯ Yes ◯ No
Please ,Provide Type	_____
Please ,Provide the Dose	_____
Antibiotic?	◯ Yes ◯ No ◯ NA
Dose	_____
Type	_____
Is the patient take another antibiotic?	◯ Yes ◯ No ◯ NA
Antibiotic_2 Type	_____
Antibiotic_2 Dose	_____
Antibiotic_3 Type	_____
Antibiotic_3 Dose	_____

Confidential

Antibiotic_4 Type	_____
Antibiotic_4 Dose	_____
Convalescent plasma?	◯ Yes ◯ No ◯ N/A
Specify	_____
Corticosteriod?	◯ Yes ◯ No
Dose	_____
Type	_____
Duration	_____

Confidential

Outcome

Outcome at Day 14	
Outcome at day 14:	☐ Alive ☐ Hospitalization ☐ Transfer to other facility ☐ Death ☐ Unknown
Outcome Date	_____
Hospital Discharge Date	_____

Outcome at Day 28	
Outcome at Day 28	◯ Alive ◯ Death
Outcome Date	_____

Confidential

Adverse Drug Reaction

Allergic Reaction	
Day	_____
Skin Rash/Urticaria	◯ No ◯ 1 ◯ 2 ◯ 3
Bronchospasm	◯ No ◯ 1 ◯ 2 ◯ 3
Dyspnea	◯ No ◯ 1 ◯ 2 ◯ 3
Tongue Edema	◯ No ◯ 1 ◯ 2 ◯ 3
Local Skin Necrosis at the Injection Site	◯ No ◯ 1 ◯ 2 ◯ 3
OtherI	◯ No ◯ 1 ◯ 2 ◯ 3
Specify,	_____
OtherII	◯ No ◯ 1 ◯ 2 ◯ 3
Specify,	_____
Gastrointestinal	
Diarrhea	◯ No ◯ 1 ◯ 2 ◯ 3 ◯ 4 ◯ 5
Dysgeusia	◯ No ◯ 1 ◯ 2 ◯ 3 ◯ 4 ◯ 5
Nausea	◯ No ◯ 1 ◯ 2 ◯ 3 ◯ 4 ◯ 5
Vomiting	◯ No ◯ 1 ◯ 2 ◯ 3 ◯ 4 ◯ 5
Abdominal Pain	◯ No ◯ 1 ◯ 2 ◯ 3 ◯ 4 ◯ 5

Confidential

OtherI	◯ No ◯ 1 ◯ 2 ◯ 3 ◯ 4 ◯ 5
Specify,	_____
OtherII	◯ No ◯ 1 ◯ 2 ◯ 3 ◯ 4 ◯ 5
Specify,	_____
Central Nervous System	
Headache	◯ No ◯ 1 ◯ 2 ◯ 3
Insomnia	◯ No ◯ 1 ◯ 2 ◯ 3
Psychosis	◯ No ◯ 1 ◯ 2 ◯ 3 ◯ 4 ◯ 5
Depression	◯ No ◯ 1 ◯ 2 ◯ 3 ◯ 4 ◯ 5
Mania	◯ No ◯ 1 ◯ 2 ◯ 3 ◯ 4 ◯ 5
ECG: QT Interval Changes	◯ No ◯ 1 ◯ 2 ◯ 3 ◯ 4 ◯ 5
OtherI	◯ No ◯ 1 ◯ 2 ◯ 3 ◯ 4 ◯ 5
Specify,	_____
OtherII	◯ No ◯ 1 ◯ 2 ◯ 3 ◯ 4 ◯ 5
Specify,	_____