

## An international randomised trial of additional treatments for COVID-19 in hospitalised patients who are all receiving the local standard of care

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### **Main Information**

Primary registry identifying number

LBCTR2020043495

MOH registration number

Study registered at the country of origin

Type of registration

Prospective

Date of registration in national regulatory

22/04/2020

**Primary sponsor** 

Date of registration in primary registry

20/10/2020

**Public title** 

An international randomised trial of additional treatments for COVID-19 in hospitalised patients who are all receiving the local

standard of care

Scientific title

An international randomised trial of additional treatments for COVID-19 in hospitalised patients who are all receiving the local standard of care

Brief summary of the study: English

It is an international study to compare the effects on major outcomes in hospital of the local standard of care alone versus the local standard of care plus one of four alternative anti-viral agents. WHO expert groups advised that four re-purposed drugs Remdesivir, Lopinavir (given with Ritonavir, to slow hepatic degradation), Interferon (β1a), and chloroquine or hydroxychloroquine should be evaluated in an international randomised trial. The main objective of this large international randomised trial is to provide reliable estimates on any effects of these anti-viral treatments on in-hospital mortality in moderate and in severe COVID.

The arm using chloroquine or hydroxychloroquine was suspended.

Brief summary of the study: Arabic

، لا توجد حالياً لقاحات أو علاجات مرخصة لمرض كوفيد. ورغم أن بعض الأدوية المستعملة لأمراض أخرى قد تساعد قليلاً في بعض الحالات فإنها قد لا تفيد فيها جميعًا. ولذلك تجري منظمة الصحة العالمية نراسة في العديد من البلدان للمقارنة بين بعض هذه الأدوية المستخدمة واستنتاج و (Lopinavir) لابينافير , (Remdesivir) مدى فاندتها في علاج مرض كوفيد. الادوية التي شيتُم استخدامها في الدراسة هي. رمديسيفير . كلوروكينّ أوهيدّروكسكلوروكين ,(İnterferon) إنترفيرون , ̈(Ritonavir) ريتونافير تم ايقاف استخدام كلوروكين أوهيدروكسكلوروكين في الدراسة

Protocol number

Solidarity-Lebanon2020

Study registered at the country of origin: Specify

Type of registration: Justify

N/A

Primary sponsor: Country of origin

Switzerland

Date of registration in national regulatory agency

22/04/2020

Acronym

SOI IDARITY

Acronym

SOLIDARITY



Health conditions/problem studied: Specify

COVID-19

Interventions: Specify

Local standard of care alone, OR local standard of care plus one of:

Remdesivir

Chloroquine or hydroxychloroquine (suspended)

Lopinavir with Ritonavir (suspended)

Lopinavir with Ritonavir plus interferon (suspended)

Interferon arm alone is added (and then suspended)

### Key inclusion and exclusion criteria: Inclusion criteria

Eligibility: consenting adults (age ≥18) hospitalised with definite COVID-19, not already receiving any of the study drugs, without known allergy or contra-indications to any of them (in the view of the physician responsible for their care), and without anticipated transfer within 72 hours to a non-study hospital. Patients invited to join the study will be those who are admitted to a collaborating hospital; no wider recruitment efforts are expected.

Key inclusion and exclusion criteria: Gender

Key inclusion and exclusion criteria: Specify gender

Both

Key inclusion and exclusion criteria: Age minimum

Key inclusion and exclusion criteria: Age maximum

18

Key inclusion and exclusion criteria: Exclusion criteria

Exclusion from study entry: Patients will not be randomised if, in the view of the randomising doctor, ANY of the AVAILABLE study drugs are contra-indicated (eg, because of patient characteristics, chronic liver or heart disease, or some concurrent medication).

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N/A

N/A

Type of study

Interventional

Type of intervention Type of intervention: Specify type

Pharmaceutical

Trial scope Trial scope: Specify scope

Therapy

Study design: Allocation Study design: Masking

Randomized controlled trial Open (masking not used)

Study design: Control Study phase
Active 3

Study design: Purpose Study design: Specify purpose

Treatment N/A

Study design: Assignment Study design: Specify assignment

IMP has market authorization IMP has market authorization: Specify

NO .

Name of IMP Year of authorization Month of authorization

Type of IMP

Remdesivir

Others

Parallel

Pharmaceutical class



Anti-vira Treatment; four re-purposed drugs to be used in the study some of them are already registered in Lebanon and used for other conditions

Therapeutic indication

anti-viral treatment

Therapeutic benefit

Treatment of Covid-19 hospitalized patients

Study model Study model: Explain model

N/A N/A

Study model: Specify model

N/A

Time perspective Time perspective: Explain time perspective

N/A

Time perspective: Specify perspective

N/A

Target follow-up duration Target follow-up duration: Unit

Number of groups/cohorts

Biospecimen retention Biospecimen description

None retained None retained for the purpose of this study

Target sample size Actual enrollment target size

1000

Date of first enrollment: Type Date of first enrollment: Date

27/04/2020 Anticipated

Date of study closure: Date Date of study closure: Type

01/04/2021 Anticipated

Recruitment status **Recruitment status: Specify** 

Date of completion

IPD sharing statement plan IPD sharing statement description

Yes

Pending



All data will be entered into a database created by WHO

Additions	ctch la	HDI

Admin comments

**Trial status** 

Approved

Secondary Identifying Numbers	
Full name of issuing authority	Secondary identifying number
NA	NA

Sources of Monetary or Material Support	
Name	
Sanofi	
Abbvie	
Gilead	
Merck	

### **Secondary Sponsors**

Name

Lebanese Ministry of Public Health

Contact for Public/Scientific Queries						
Contact type	Contact full name	Address	Country	Telephone	Email	Affiliation
Public	Rasha Hamra	Beirut	Lebanon	01-830300	rashahamra@ya hoo.com	МОРН
Scientific	Pierre Abi Hana	Beirut	Lebanon	03-611221	boutrosh@hotma il.com	RHGH



Centers/Hospitals Involved in the Study			
Center/Hospital name	Name of principles investigator	Principles investigator speciality	Ethical approval
Rafic Hariri Govermental Hospital	Pierre Abi Hana	Infectious Disease	Approved
Notre Dame Des Secours	Madona Mattar	Infectious Disease	Approved
Lebanese Univeristy of Beirut Medical Center- Rizk Hospital	Roula Husni Samaha	Infectious Disease	Approved
Hotel Dieu de France	Moussa Riachi	Pulmonary	Approved
Mount Lebanon Hospital	Nadine Yared	Infectious Disease	NA

Ethics Review				
Ethics approval obtained	Approval date	Contact name	Contact email	Contact phone
Rafic Hariri University Hospital	09/04/2020	lyad Issa	iyadissa71@gmail.com	01-830000
Notre Dame des Secours Centre Hospitalier Universitaire	01/04/2020	Wissam Khourt	info@chu-nds.org	09-940400
Lebanese American University- University Medical Center Rizk Hospital	22/04/2020	Joseph Stephan	irb@lau.edu.lb	09-547254, ext:2340
Hotel Dieu de France	21/04/2020	Nancy Alam	nancy.alam@usj.edu.lb	01-421000, ext:2334

## **Countries of Recruitment** Name Lebanon

Health Conditions or Problems Studied		
Condition	Code	Keyword
Covid-19	Coronavirus infection, unspecified (B34.2)	Covid-19



Interventions		
Intervention	Description	Keyword
Standard Care	as per the hospital standards	standard care
Remdesivir	Daily infusion for 10 days	Remdesivir

Primary Outcomes		
Name	Time Points	Measure
All-cause mortality, subdivided by severity of disease at the time of randomisation	At discharge or death	Discharge date or Cause of death

Key Secondary Outcomes			
Name	Time Points	Measure	
Assess any effects of these anti-viral treatments on hospital duration and receipt of ventilation or intensive care	During Hospitalization while on treatment	Clinical improvement	
Identify any serious adverse reactions	During Hospitalization while on treatment	Any serious unexpected adverse reaction that is life- threatening (e.g. anaphylaxis, Stevens-Johnson syndrome, aplastic anaemia, or anything comparably strange) must be reported within 24 hours	
Virological cure	After Treatment is finalized	PCR negative twice within 48hours	



Trial Results	
Summary results	
Study results globally	
Date of posting of results summaries	Date of first journal publication of results
Results URL link	
Baseline characteristics	
Participant flow	
Adverse events	
Outcome measures	
URL to protocol files	