



# 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

### Protocol number

Solidarity-Lebanon2020

### MOH registration number

### Study registered at the country of origin

Yes

### Study registered at the country of origin: Specify

### Type of registration

Prospective

### Type of registration: Justify

N/A

### Date of registration in national regulatory agency

22/04/2020

### Primary sponsor

WHO

### Primary sponsor: Country of origin

Switzerland

### Date of registration in primary registry

23/04/2020

### Date of registration in national regulatory agency

22/04/2020

### Public title

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

### Acronym

SOLIDARITY

### Scientific title

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

### Acronym

SOLIDARITY

### 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 ( $\beta$ 1a), 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.

### 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 جميعاً. ولذلك تجري منظمة الصحة العالمية دراسة في العديد من البلدان للمقارنة بين بعض هذه الأدوية المستخدمة واستنتاج و (Lopinavir) لايفنافير , (Remdesivir) مدى فائدتها في علاج مرض كوفيد. الأدوية التي سيتم استخدامها في الدراسة هي: ريميديسيفير (Remdesivir) , ريتونايفير (Ritonavir) , إنترفرون (Interferon) , كلوروكين أو هيدروكسكلوروكين.

### 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  
Lopinavir with Ritonavir  
Lopinavir with Ritonavir

## Key inclusion and exclusion criteria: Inclusion criteria

Eligibility: consenting adults (age  $\geq 18$ ) 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

Both

## Key inclusion and exclusion criteria: Specify gender

## Key inclusion and exclusion criteria: Age minimum

18

## Key inclusion and exclusion criteria: Age maximum

99

## 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).

## Type of study

Interventional

## Type of intervention

Pharmaceutical

## Type of intervention: Specify type

N/A

## Trial scope

Therapy

## Trial scope: Specify scope

N/A

## Study design: Allocation

Randomized controlled trial

## Study design: Masking

Open (masking not used)

## Study design: Control

Active

## Study phase

3

## Study design: Purpose

Treatment

## Study design: Specify purpose

N/A

## Study design: Assignment

Parallel

## Study design: Specify assignment

N/A

## IMP has market authorization

No

## IMP has market authorization: Specify

## Name of IMP

Remdesivir

## Year of authorization

## Month of authorization

## Type of IMP

Others

## 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**

N/A

**Study model: Explain model**

N/A

**Study model: Specify model**

N/A

**Time perspective**

N/A

**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**

None retained

**Biospecimen description**

None retained for the purpose of this study

**Target sample size**

1000

**Actual enrollment target size**

**Date of first enrollment: Type**

Anticipated

**Date of first enrollment: Date**

27/04/2020

**Date of study closure: Type**

Anticipated

**Date of study closure: Date**

01/04/2021

**Recruitment status**

Pending

**Recruitment status: Specify**

**Date of completion**

**IPD sharing statement plan**

Yes

**IPD sharing statement description**

All data will be entered into a database created by WHO



Additional data URL

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@yahoo.com	MOPH
Scientific	Pierre Abi Hana	Beirut	Lebanon	03-611221	boutrosh@hotmail.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	Iyad 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 as the cause of diseases classified to other chapters (B97.2)	Covid-19



## Interventions

Intervention	Description	Keyword
Standard Care	as per the hospital standards	standard care
Remdesivir	Daily infusion for 10 days	Remdesivir
Chloroquine or hydroxychloroquine	Two oral loading doses, then orally twice daily for 10 days	Chloroquine or hydroxychloroquine
Lopinavir with Ritonavir	Orally twice daily for 14 days	Lopinavir with Ritonavir
Lopinavir with Ritonavir (ditto) plus Interferon	Interferon: daily injection for 6 days	Lopinavir with Ritonavir plus Interferon

## 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