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
13/07/2020

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 (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 جميعا. ولذلك تجري منظمة الصحة العالمية دراسة في العديد من البلدان للمقارنة بين بعض هذه الأدوية المستخدمة واستنتاج مدى فائدتها في علاج مرض كوفيد. الادوية التي شيتم استخدامها في الدراسة هي: رمديسيفير (Remdesivir) , لابينافير (Lopinavir) و ريتونافير (Ritonavir) , إنترفيرون (Interferon), كلوروكين أوهيدروكسكلوروكين .
تم ايقاف استخدام كلوروكين أوهيدروكسكلوروكين في الدراسة.

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 (was suspended)
Lopinavir with Ritonavir (suspended)
Lopinavir with Ritonavir plus interferon (suspended)
Interferon arm alone is added

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

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 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
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