



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

23/06/2020

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 (β 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. 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 جميعاً. ولذلك تجري منظمة الصحة العالمية دراسة في العديد من البلدان للمقارنة بين بعض هذه الأدوية المستخدمة واستنتاج و (Lopinavir) لابينايفير , (Remdesivir) مدى فائدتها في علاج مرض كوفيد. الأدوية التي سيتم استخدامها في الدراسة هي: رمديسيفير , كلوروكين أو هيدروكسكلوروكين , (Interferon) إنترفيرون , (Ritonavir) ريتونايفير . تم إيقاف استخدام كلوروكين أو هيدروكسكلوروكين 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
Lopinavir with Ritonavir

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 Governmental 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