Clinical trial results:
Treatment of Coronavirus SARS-Cov2 Respiratory Infections with Hydroxychloroquine

Summary

EudraCT number	2020-000890-25
Trial protocol	FR
Global end of trial date	25 March 2020

Results information

Result version number	v1 (current)
This version publication date	01 November 2022
First version publication date	01 November 2022

Trial information

Trial identification

Sponsor protocol code	202002102

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	-
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Fondation Méditerranée Infection
Sponsor organisation address	19-21 boulevard jean moulin, marseille, France, 13005
Public contact	IHU Méditerranée Infection, Fondation Méditerranée Infection (FMI) - IHU Méditerranée Infection, 0033 4 13 73 23 47, direction.ihu@mediterranee-infection.com
Scientific contact	IHU Méditerranée Infection, Fondation Méditerranée Infection (FMI) - IHU Méditerranée Infection, 0613637651 4 13 73 23 47, direction.ihu@mediterranee-infection.com

Notes:

Paediatric regulatory details

Is trial part of an agreed paediatric investigation plan (PIP)	No
Does article 45 of REGULATION (EC) No 1901/2006 apply to this trial?	No
Does article 46 of REGULATION (EC) No 1901/2006 apply to this trial?	No

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	05 May 2020
Is this the analysis of the primary completion data?	Yes
Primary completion date	25 March 2020
Global end of trial reached?	Yes
Global end of trial date	25 March 2020
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To shorten the period of virus sheding and thus contagion

Protection of trial subjects:

Monitoring will be as usual for short-term Plaquenil prescriptions, essentially three times a week monitoring of blood sugar and potassium levels. Drugs which may prolong the QT should only be prescribed if absolutely necessary.
In addition, serum hydroxychloroquine levels should be monitored twice a week in order to control residual levels and to adapt the dosage (target 1 to 2 µg/L).

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	06 March 2020
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	No

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	France: 24
Worldwide total number of subjects	24
EEA total number of subjects	24

Notes:

Subjects enrolled per age group

In utero	0
Preterm newborn - gestational age < 37 wk	0
Newborns (0-27 days)	0
Infants and toddlers (28 days-23 months)	0
Children (2-11 years)	0
Adolescents (12-17 years)	0
Adults (18-64 years)	19
From 65 to 84 years	5
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Patients hospitalised in the APHM, for whom a diagnosis of SARS-CoV2 respiratory infection will be made on a pharyngeal swab or a deep respiratory sample by the IHU laboratory, will be contacted and offered to participate in the protocol, after having been expressly informed of the risks and expected benefits of Hydroxychloroquine treatment

Pre-assignment

Screening details:

Patients with coronavirus disease COVID-19
Adults (18-64 years)
Elderly (>= 65 years)

Period 1

Period 1 title	5th march 2020 (overall period)
Is this the baseline period?	Yes
Allocation method	Non-randomised - controlled
Blinding used	Not blinded

Arms

Arm title	Experimental group

Arm description:

Patients treated by hydroxychloroquine

Arm type	Experimental
Investigational medicinal product name	Plaquenil 200 mg, comprimé pelliculé
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Coated tablet
Routes of administration	Oral use

Dosage and administration details:

600 mg per day

Number of subjects in period 1	Experimental group
Started	24
Completed	21
Not completed	3
Consent withdrawn by subject	1
intensive care unit on day 1 for complications	2

Baseline characteristics

Reporting groups	
Reporting group title	5th march 2020

Reporting group description: -

Reporting group values	5th march 2020	Total	
Number of subjects	24	24	
Age categorical Units: Subjects			
In utero	0	0	
Preterm newborn infants (gestational age < 37 wks)	0	0	
Newborns (0-27 days)	0	0	
Infants and toddlers (28 days-23 months)	0	0	
Children (2-11 years)	0	0	
Adolescents (12-17 years)	0	0	
Adults (18-64 years)	19	19	
From 65-84 years	5	5	
85 years and over	0	0	
Gender categorical Units: Subjects			
Female	10	10	
Male	14	14	

End points

End points reporting groups

Reporting group title	Experimental group
Reporting group description:	
Patients treated by hydroxychloroquine	

Primary: Results of SARS-COV2 virus detection at day 1

End point title	Results of SARS-COV2 virus detection at day 1[1]

End point description:

21 patients analysed for the primary endpoint "virus detection". These were the 21 patients who took the experimental treatment in accordance with the conditions set out in the clinical trial (dosage, duration, hospitalisation at the IHU, etc.).

End point type	Primary

End point timeframe:

Day 1 after treatment

Notes:

[1] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: It is a descriptif study with 1 arm, there is no inference statistics results.

End point values	Experimental group			
Subject group type	Reporting group			
Number of subjects analysed	21			
Units: 24 %	21			

Statistical analyses

No statistical analyses for this end point

Primary: Results of SARS-COV2 virus detection at day 4

End point title	Results of SARS-COV2 virus detection at day 4[2]

End point description:

21 patients analysed for the primary endpoint "virus detection". These were the 21 patients who took the experimental treatment in accordance with the conditions set out in the clinical trial (dosage, duration, hospitalisation at the IHU, etc.).

End point type	Primary

End point timeframe:

Day 4 after treatment

Notes:

[2] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: It is a descriptif study with 1 arm, there is no inference statistics results.

End point values	Experimental group			
Subject group type	Reporting group			
Number of subjects analysed	21			
Units: 52 %	21			

Statistical analyses

No statistical analyses for this end point

Primary: Results of SARS-COV2 virus detection at day 7

End point title	Results of SARS-COV2 virus detection at day 7[3]

End point description:

21 patients analysed for the primary endpoint "virus detection". These were the 21 patients who took the experimental treatment in accordance with the conditions set out in the clinical trial (dosage, duration, hospitalisation at the IHU, etc.).

End point type	Primary

End point timeframe:

Day 7 after treatment

Notes:

[3] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: It is a descriptif study with 1 arm, there is no inference statistics results.

End point values	Experimental group			
Subject group type	Reporting group			
Number of subjects analysed	21			
Units: 60 %	24			

Statistical analyses

No statistical analyses for this end point

Primary: Results of SARS-COV2 virus detection at day 14

End point title	Results of SARS-COV2 virus detection at day 14[4]

End point description:

21 patients analysed for the primary endpoint "virus detection". These were the 21 patients who took the experimental treatment in accordance with the conditions set out in the clinical trial (dosage, duration, hospitalisation at the IHU, etc.).

End point type	Primary

End point timeframe:

Day 14 after treament

Notes:

[4] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: It is a descriptif study with 1 arm, there is no inference statistics results.

End point values	Experimental group			
Subject group type	Reporting group			
Number of subjects analysed	21			
Units: 100 %	21			

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

- one nausea
- 2 patients were transferred to the intensive care unit on day 1 for complications of the disease (adaptation or discontinuation of the experimental treatment).

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	23

Reporting groups

Reporting group title	Experimental group

Reporting group description: -

Serious adverse events	Experimental group		
Total subjects affected by serious adverse events			
subjects affected / exposed	2 / 24 (8.33%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events	0		
Respiratory, thoracic and mediastinal disorders			
Intensive care			
subjects affected / exposed	2 / 24 (8.33%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		

Frequency threshold for reporting non-serious adverse events: 1 %

Non-serious adverse events	Experimental group		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	1 / 24 (4.17%)		
Gastrointestinal disorders			
Nausea			
subjects affected / exposed	1 / 24 (4.17%)		
occurrences (all)	1		

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? No

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported