



## Clinical trial results:

### The effect of hydroxychloroquine sulphate on hedonic food intake, appetite-related sensations and gastrointestinal hormone release in healthy female subjects

#### Summary

EudraCT number	2018-003083-30
Trial protocol	BE
Global end of trial date	22 October 2020

#### Results information

Result version number	v1 (current)
This version publication date	10 February 2021
First version publication date	10 February 2021
Summary attachment (see zip file)	Data plaquenil study (PLAQHV data.docx)

#### Trial information

##### Trial identification

Sponsor protocol code	PLAQHV
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##### Additional study identifiers

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

Notes:

#### Sponsors

Sponsor organisation name	TARGID
Sponsor organisation address	Herestraat 49, Leuven, Belgium, 3000
Public contact	TARGID, KU Leuven, +32 16344225, jan.tack@kuleuven.be
Scientific contact	TARGID, KU Leuven, +32 16344225, jan.tack@kuleuven.be

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:

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**Results analysis stage**

Analysis stage	Final
Date of interim/final analysis	14 December 2020
Is this the analysis of the primary completion data?	Yes
Primary completion date	22 October 2020
Global end of trial reached?	Yes
Global end of trial date	22 October 2020
Was the trial ended prematurely?	No

Notes:

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**General information about the trial**

Main objective of the trial:

To detect changes in hedonic food intake after acute administration of hydroxychloroquine sulphate compared to placebo.

Protection of trial subjects:

Identification of trial subjects was protected by the implementation of subject identification numbers

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	24 September 2018
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	No

Notes:

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**Population of trial subjects**

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**Subjects enrolled per country**

Country: Number of subjects enrolled	Belgium: 10
Worldwide total number of subjects	10
EEA total number of subjects	10

Notes:

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**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)	10
From 65 to 84 years	0
85 years and over	0

## Subject disposition

### Recruitment

Recruitment details: -

### Pre-assignment

Screening details:

Healthy volunteers were included for this study.

### Period 1

Period 1 title	Overall trial (overall period)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator

### Arms

Are arms mutually exclusive?	No
<b>Arm title</b>	Plaquenil

Arm description: -

Arm type	Experimental
Investigational medicinal product name	Hydroxychloroquine sulphate
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

2 tablets of 200mg hydroxychloroquine sulphate

<b>Arm title</b>	Placebo
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Arm description: -

Arm type	Placebo
Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

2 placebo tablets

<b>Number of subjects in period 1</b>	Plaquenil	Placebo
Started	10	10
Completed	10	10



## Baseline characteristics

### Reporting groups

Reporting group title	Overall trial (overall period)
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Reporting group description: -

Reporting group values	Overall trial (overall period)	Total	
Number of subjects	10	10	
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)	10	10	
From 65-84 years	0	0	
85 years and over	0	0	
Age continuous			
Units: years			
arithmetic mean	23.8		
full range (min-max)	20 to 27	-	
Gender categorical			
Units: Subjects			
Female	10	10	
Male	0	0	

## End points

### End points reporting groups

Reporting group title	Plaquenil
Reporting group description: -	
Reporting group title	Placebo
Reporting group description: -	

### Primary: Changes of hunger from baseline

End point title	Changes of hunger from baseline
End point description:	
End point type	Primary
End point timeframe:	
Comparison between visit 1 and visit 2	

End point values	Plaquenil	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	10	10		
Units: mm				
arithmetic mean (standard error)	5.6 ( $\pm$ 3.1)	6.7 ( $\pm$ 4.2)		

### Statistical analyses

Statistical analysis title	Mixed models for hunger
Comparison groups	Plaquenil v Placebo
Number of subjects included in analysis	20
Analysis specification	Pre-specified
Analysis type	non-inferiority
P-value	= 0.044
Method	ANOVA

## Adverse events

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### Adverse events information<sup>[1]</sup>

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Timeframe for reporting adverse events:

From signing the informed consent until the end of visit 2.

Assessment type	Non-systematic
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### Dictionary used

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Dictionary name	MedDRA
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Dictionary version	23
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Frequency threshold for reporting non-serious adverse events: 5 %

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### Notes:

[1] - There are no non-serious adverse events recorded for these results. It is expected that there will be at least one non-serious adverse event reported.

Justification: Hunger and headache were reported in this study during both conditions. This was due to the study protocol, subjects needed to be fasted, and not due to the administration of the investigation medicinal product.

## More information

### Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? No

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### Interruptions (globally)

Were there any global interruptions to the trial? No

### Limitations and caveats

None reported