# 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 |

**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:

## 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:

## 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:

## Population of trial subjects

### Subjects enrolled per country

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

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) | 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 |
| **Arm title** | 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

| | |
|---|---|
| **Arm title** | Placebo |

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

| **Number of subjects in period 1** | Plaquenil | Placebo |
|---|---|---|
| Started | 10 | 10 |
| Completed | 10 | 10 |

## Baseline characteristics

### Reporting groups

| Reporting group title | Overall trial (overall period) |
|---|---|

Reporting group description: -

| Reporting group values | Overall trial (overall period) | Total | |
|---|---|---|---|
| Number of subjects | 10 | 10 | |
| Age categorical<br>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<br>Units: years | | | |
| arithmetic mean | 23.8 | | |
| full range (min-max) | 20 to 27 | - | |
| Gender categorical<br>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 (± 3.1) | 6.7 (± 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

| Adverse events information[1] | |
|---|---|
| Timeframe for reporting adverse events: From signing the informed consent until the end of visit 2. | |
| Assessment type | Non-systematic |

| Dictionary used | |
|---|---|
| Dictionary name | MedDRA |
| Dictionary version | 23 |

Frequency threshold for reporting non-serious adverse events: 5 %

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

### Interruptions (globally)

Were there any global interruptions to the trial? No

### Limitations and caveats

None reported