Psychosis and psychotic disorders” and “Depression and suicide/self-injury” following exposure to Hydroxychloroquine and chloroquine

First published: 27/08/2020

Last updated: 02/04/2024

Study Finalised

Administrative details

PURI

https://redirect.ema.europa.eu/resource/37083

EU PAS number

EUPAS36912

Study ID

37083

DARWIN EU® study

No

Study countries

Germany

Study description

Hydroxychloroquine (HCQ) and chloroquine (CQ) are nationally authorised 4-aminoquinoline antimalarial agents originally developed as less toxic alternatives to quinine. Both have risen to prominence in the earlier months of 2020 as potential treatments in the current COVID-19 pandemic. In May 2020, the Spanish regulatory Agency (AEMPS) warned about the occurrence of neuropsychiatric reactions associated with intake of HCQ and CQ in patients being treated for COVID-19. This new information let to initiation of a signal procedure at the European Union's Pharmacovigilance Risk Assessment Committee (PRAC) and led to further review of data pertaining to the association of neuropsychiatric reactions with chloroquine/hydroxychloroquine. Analyses of healthcare records held at the EMA has supported further analyses of data relating to this signal. This study has considered data recorded in the electronic electronic health records database: IMS ® Disease Analyzer Germany (IMS-Germany). It looks at the risk of "Psychosis and psychotic disorders" and "Depression and suicide/self-injury" following exposure to Hydroxychloroquine and Chloroquine.

Study status

Finalised

Research institution and networks

Institutions

European Medicines Agency (EMA)

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Institution

Contact details

Study institution contact

Valerie Strassmann

Study contact

valerie.strassmann@ema.europa.eu

Primary lead investigator

Karin Hedenmalm

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 01/07/2020

Actual: 01/07/2020

Study start date

Planned: 01/07/2020

Actual: 01/07/2020

Date of final study report

Planned: 27/08/2020

Actual: 27/08/2020

Sources of funding

- EMA

Regulatory

Was the study required by a regulatory body?

Yes

Is the study required by a Risk Management Plan (RMP)?

Not applicable

Methodological aspects

Study type

Study type list

Study topic:

Human medicinal product

Disease /health condition

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Drug utilisation

Data collection methods:

Secondary use of data

Main study objective:

The study has the following objectives :1. To describe the pattern of use of HCQ and CQ.2. To estimate the incidence rate of recorded events as coded in primary care records whilst exposed and at any time following exposure to HCQ and CQ.a. Suicidalityb. Self-endangering behaviour (including self-harm)c. Affective, Psychosis and psychotic disordersd. Non-psychotic depression

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Study drug International non-proprietary name (INN) or common name

HYDROXYCHLOROQUINE

CHLOROQUINE

Medical condition to be studied

Reactive psychosis

Psychotic behaviour

Depression

Suicide attempt

Intentional self-injury

Additional medical condition(s)

Suicidality, Self-endangering behaviour, Psychotic disorders, Non-psychotic depression and other emotional disorders

Population studied

Short description of the study population

The population eligible for the study consists of all patients in IMS ® Disease Analyzer Germany with an observation period of one-year or more at the time of their first prescription for HCQ or CQ. Patients are followed until their last consultation, or, in case of interruptions in consultation lasting 366 days or longer, follow-up will end on day 365 after the consultation immediately prior to the interruption. The study subjects are followed from the first use of Hydroxychloroquine and Chloroquine on the database (1992 onwards) to most recent data available (December 2019). In any case data do not cover data collected from the ongoing COVID19 pandemic.

Age groups

Infants and toddlers (28 days – 23 months)

Children (2 to < 12 years)

Adolescents (12 to < 18 years)

Adults (18 to < 46 years)

Adults (46 to < 65 years)

Adults (65 to < 75 years)

Adults (75 to < 85 years)

Adults (85 years and over)

Estimated number of subjects

55000

Study design details

Outcomes

To describe the pattern of use of HCQ and CQ. To estimate the incidence rate of recorded events as coded in primary care records whilst exposed and at any time following exposure to HCQ and CQ.a. Suicidalityb. Self-endangering

behaviour (including self-harm)c. Affective, Psychosis and psychotic disordersd. Non-psychotic depression

Data analysis plan

All of the descriptive analyses in the study were performed by the authors based on data available in IMS® Disease Analyzer Germany and THIN IMRD UK. Incidence rates were calculated as the number of events occurring during follow-up divided by the person years of follow-up with 95% confidence intervals.

Documents

Study results

HCQ-CQ- Psychiatric events - EMA report on results - Germany.pdf(2.36 MB)

Data management

ENCePP Seal

Conflicts of interest of investigators

HCQ-CQ- Psychiatric events - EMA report on results - UK.pdf(1.12 MB)

Data sources

Data source(s)

THIN® (The Health Improvement Network®)

Data source(s), other

IQVIA Disease Analyzer Germany

Data sources (types)

Electronic healthcare records (EHR)

Use of a Common Data Model (CDM)

CDM mapping

No

Data quality specifications

Check conformance

Unknown

Check completeness

Unknown

Check stability

Unknown

Check logical consistency

Unknown

Data characterisation

Data characterisation conducted

No