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A research study of the role of chloroquine in treating patients with dengue

Submission date
10/11/2006

Recruitment status
No longer recruiting

Registration date
21/11/2006

Overall study status
Completed

Last Edited
05/02/2015

Condition category
Infections and Infestations

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
This study aims to find out whether chloroquine reduces the number of dengue viruses in a patient with a dengue infection. Dengue fever is the most common mosquito-transmitted viral disease in humans. Severe forms of dengue infection can result in dengue hemorrhagic fever (DHF) and dengue shock syndrome (DSS). Currently, no vaccine or treatment exists except for supportive care. Studies have shown that the dengue virus needs a certain level of acidity (or pH) in order to enter into human cells. Chloroquine is a drug known to affect other viruses that require a pH-dependent step to enter human cells. Therefore, this study will test whether chloroquine shows potential to be a treatment for dengue-infected patients by reducing the number of viruses that infect cells.

Who can participate?
Eligible patients have uncomplicated signs of dengue fever (fever, headache, aches, rash) after a standard clinical examination, with a history of symptoms less than 5 days. They must be over 14 years of age and weigh more than 45 kg, with no previous history of hypersensitivity to chloroquine, and cannot be pregnant or be receiving therapy for other disorders.

What does the study involve?
Prior to recruitment, all patients will have a standard clinical examination, a chest x-ray and a blood test to count the number of dengue viruses. The patients will then be randomly allocated to either group A or group B. Group A patients will receive chloroquine treatment and group B patients will receive a placebo (dummy) tablet. The study will then compare dengue outcomes in patients receiving placebo versus chloroquine by measuring fever clearance time and the time until tests show no presence of dengue virus. All adverse events will be fully recorded including duration, severity, outcome and relationship to study drug. Liver function tests will be repeated at discharge in all patients.

What are the possible benefits and risks of participating?
The Oxford University Clinical Research Unit will provide the drugs and support for the trial, and all patients will receive standard dengue clinical examination, diagnosis and treatment. Chloroquine side effects include nausea, vomiting, diarrhea, abdominal cramps and headache.

Where is the study run from?
The study is run by researchers at the Oxford University Clinical Research Unit (Viet Nam) and the Hospital for Tropical Diseases (Ho Chi Minh City, Viet Nam).

When is the study starting and how long is it expected to run for?
The study began in July 2006 and ended in March 2008.

Who is funding the study?
The Wellcome Trust (UK).

Who is the main contact?
The Clinical Trials Unit at the Oxford University Clinical Research Unit - Viet Nam
Tel: +84 (0)839 241 983

Contact information

Type(s)
Scientific

Contact name
Dr Cameron Simmons

Contact details
Oxford University Clinical Research Unit
Hospital for Tropical Diseases
Ho Chi Minh City
Viet Nam
District 5
+84 (0)8 9237954
csimmons@oucru.org

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
061330

Study information

Scientific Title
A randomised, double-blind, placebo-controlled trial of chloroquine for treatment of dengue

Acronym
EF

Study objectives
The primary purpose of this protocol is to evaluate chloroquine as compared to placebo in the treatment of dengue with the hypothesis that chloroquine will decrease viral replication and therefore may confer a clinical advantage. This protocol will also attempt to define differences in clinical manifestations, the relationship between chloroquine concentrations and viral dynamics, and the pathogenesis of dengue, which may help to improve the treatment of this disease.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Hospital for Tropical Diseases, 20/04/2006
2. Oxford Tropical Research Ethical Committee, 23/02/2006, ref: 005-06

Study design
Double-blind randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Dengue fever

Interventions
Patients will receive placebo (starch) or 600 mg chloroquine on day one and two, then 300 mg on day three. Delivery is by oral ingestion.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Chloroquine

Primary outcome measure

The primary objective is to compare the antiviral efficacy of chloroquine in the treatment of dengue infections as assessed by negative Reverse Transcriptase (RT)-Polymerase Chain Reaction (PCR) detection of viral Ribonucleic Acid (RNA) in plasma and clearance of NS-1 from blood.

Secondary outcome measures
No secondary outcome measures

Overall study start date
01/07/2006

Completion date
30/03/2008

Eligibility

Key inclusion criteria
Any adult patient (either sex) with dengue who gives consent. We plan to enrol all patients with suspected dengue presenting within three days of illness onset.

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
220

Key exclusion criteria
No consent

Date of first enrolment
01/07/2006

Date of final enrolment
31/01/2008

Locations

Countries of recruitment
Viet Nam

Study participating centre

Oxford University Clinical Research Unit
Ho Chi Minh City
Viet Nam
District 5

Sponsor information

Organisation
University of Oxford (UK)

Sponsor details
University Offices
Wellington Square
Oxford
England
United Kingdom
OX1 2JD
+44 (0)1865 270143
research.services@admin.ox.ac.uk

Sponsor type
University/education

Website
http://www.ox.ac.uk

ROR
https://ror.org/052gg0110

Funder(s)

Funder type
Charity

Funder Name
Wellcome Trust

Alternative Name(s)

Funding Body Type
Private sector organisation

Funding Body Subtype
International organizations

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	10/08/2010		Yes	No