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Examining whether any interactions occur between the antibiotic Ciprofloxacin and the antimalarial treatment Chloroquine/Proguanil

Submission date 17/01/2019	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol
Registration date 05/04/2019	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 12/04/2019	**Condition category** Other	[_] Individual participant data [_] Record updated in last year

Plain English summary of protocol

Background and study aims
The aim of the study was to check whether two medicines commonly used together by military personnel affect how the medicines are absorbed and eliminated by the body and whether both medicines taken at once are well tolerated.

Who can participate?
Healthy male subjects aged between 18 and 50 years.

What does the study involve?
The study involves taking tablets (antibiotics and/or antimalarial tablets) over a three week period. People entering the study were assigned to either group 1 or group 2. People in group 1 took antibiotic tablets plus antimalarial tablets, whereas people in group 2 took antimalarial tablets.

What are the possible benefits and risks of participating?
There were no direct individual benefits for the subjects participating. All medicinal products can on occasions cause unwanted effects, but no participant experienced any significant adverse effects attributable to the medicines studied.

Where is the study run from?
The study was run from- Dstl, Porton Down, Salisbury.

When is the study starting and how long is it expected to run for?
November 2005 to June 2010.

Who is funding the study?
This study was funded by the UK Ministry of Defence.

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

Clinical Trials Information System (CTIS)
2005-004905-27

Protocol serial number
CBD VP 132/05

Study information

Scientific Title
Pharmacokinetic Interactions between Ciprofloxacin and Chloroquine/Proguanil Prophylaxis in healthy young males: a randomised, parallel-group, open label study

Study objectives
Trial rationale was to to determine whether any pharmacokinetic interactions occur during the concomitant oral administration of Chloroquine/Proguanil with Ciprofloxacin in healthy subjects.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Oxfordshire Research Ethics Committee A, 01/02/2008, ref. 07/H0604/155.

Primary study design
Interventional

Study design
Randomised, parallel-group, open label study.

Study type(s)
Other

Health condition(s) or problem(s) studied
Pharmacokinetics

Interventions

Ciprofloxacin and Chloroquine/Proguanil
Route of administration - oral
Doses- 500 mg ciprofloxacin, 200 mg proguanil, 500 mg chloroquine phosphate

Brief methodology:

Ciprofloxacin
Generic drug name: ciprofloxacin
Dosage given: 500mg
Method and frequency of administration: oral route. Ciprofloxacin was administered as 2 x 250 mg tablets orally on Day 1 and again on Day 22 to subjects in Group 1 only.
Total duration of treatment: 2 single doses separated by 21 days

Chloroquine
Generic drug name: chloroquine
Dosage given: 500mg
Chloroquine was administered as 2 x 250 mg tablets orally once a week, starting on Day 8, for 15 days (i.e. on 3 occasions) to subjects in both Groups 1 and 2. On the third occasion (Day 22) it was combined with a ciprofloxacin dose (500 mg) for subjects in Group 1 only.
Total duration of treatment: 2 weeks

Proguanil
Generic drug name: proguanil
Dosage given: 200mg
Method and frequency of administration: Proguanil was administered as 2 x 100 mg tablets orally once daily for 15 days, starting from Day 8, to subjects in both Groups 1 and 2. It was combined with a
chloroquine dose on Day 8, Day 15 and Day 22 and combined with a ciprofloxacin dose (500 mg) on Day 22 for subjects in Group 1 only.
Total duration of treatment: 2 weeks

Intervention Type
Drug

Phase
Phase IV

Drug/device/biological/vaccine name(s)
Ciprofloxacin and Chloroquine/Proguanil

Primary outcome(s)
1. Any interaction occurring with concomitant oral administration of chloroquine/proguanil with ciprofloxacin was measured using pharmacokinetic (PK) parameters at day 1, day 2, day 22, and days 23to 25. These parameters were assessed during administration of:
1.1. Chloroquine and Proguanil together
1.2. Chloroquine and Proguanil together in combination with Ciprofloxacin
1.3. Ciprofloxacin alone

Key secondary outcome(s)

1. Safety of concomitant oral administration of Chloroquine/Proguanil with Ciprofloxacin was measured using the following measures pre and post-study:
1.1. Medical History and Physical Examinations
1.2. Vital Signs (supine blood pressure and pulse rate)
1.3. Laboratory Safety Screening: haematology, biochemistry and urinalysis were carried out pre and post study.
2. Tolerability of concomitant oral administration of Chloroquine/Proguanil with Ciprofloxacin was measured using Adverse Event Recording: performed throughout the study.

Completion date
14/06/2010

Eligibility

Key inclusion criteria
1. Ability and willingness to give written informed consent prior to study participation
2. Healthy male subjects aged between 18 and 50 years (inclusive)
3. Body Mass Index (BMI) within the range of 21 and 30 kg/m2
4. Vital signs within the following ranges:
4.1. Pulse rate 40-90 bpm
4.2. Systolic blood pressure 90-140 mmHg
4.3. Diastolic blood pressure 50-90 mmHg
5. Ability to communicate well with the Investigator and to comply with the requirements of the study.

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
Male

Total final enrolment
16

Key exclusion criteria
1. Presence of any clinically significant medical condition as determined by the Investigator or Medical Advisor
2. Any clinically significant haematological or biochemical abnormality as determined by the Investigator or Medical Advisor
3. Any surgical or medical condition which might significantly alter the absorption, distribution,

metabolism or excretion of any drug (e.g. renal or liver disease, respiratory, immunological, endocrine or neurological disorders)
4. Any ECG abnormality other than sinus bradycardia or respiratory sinus arrhythmia
5. Known or suspected hypersensitivity or idiosyncratic reaction related to any of the investigational medicinal products
6. Positive test for hepatitis B surface antigen or Hepatitis C antibody
7. History or evidence of alcohol abuse defined as an intake of more than 28 units per week (4 units per day), where 1 unit corresponds to 250 mL beer, 20 mL spirits/liqueur or one glass (100 mL) of wine
8. Participation in another clinical study within the three months prior to screening
9. Use of any prescription medication within the 14 days prior to screening
10. Use of any non-prescription medication within the last 7 days (apart from paracetamol), which may, in the opinion of the Investigator or Medical Advisor, impact the safety aspects and /or objectives of the study
11. Donation of blood or blood products within the 3 months prior to screening, or the intention to donate blood or blood products within 3 months after completion of the study.

Date of first enrolment
01/02/2008

Date of final enrolment
10/10/2008

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Dstl, Porton Down
Salisbury
United Kingdom
SP40JQ

Sponsor information

Organisation
Defence Science and Technology Laboratory (Dstl)

ROR
https://ror.org/04jswqb94

Funder(s)

Funder type
Government

Funder Name
Ministry of Defence

Alternative Name(s)
MOD

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are not expected to be made available due to lack of subject consent being obtained at the time of the study.

IPD sharing plan summary
Not expected to be made available