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Coartem or Coarnate for uncomplicated malaria and parasite carriage in Rwanda

Submission date	Recruitment status	[_] Prospectively registered
23/08/2010	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
25/10/2010	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
25/10/2010	Infections and Infestations	[_] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
No.187/RNEC/2010

Study information

Scientific Title
An open labeled randomised trial of Coartem vs. Co-Arinate for uncomplicated malaria and parasite carriage in Rwanda

Acronym
CoCo Trial

Study objectives
Coarinate is as effective as coartem

Ethics approval required
Old ethics approval format

Ethics approval(s)
The Rwanda National Ethics Committee approved on the 31st of March 2010 (ref: No.187 /RNEC / 2010)

Study design
Open label randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Prevention

Participant information sheet
Not available in web format, please use contact details below to request a patient information sheet

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

Interventions
Patients will be randomised to receive

1. Coartem (arthemeter lumifantrine)
5-14 kg 20 mg arthemeter+120 mg lumefantrine 2/day for 3 days
15-24 kg: 40 mg arthemeter+ 240 mg lumefantrine 2/day for 3 days
25-34 kg: 60 mg arthemeter+360 mg lumefantrine 2/day for 3 days
34+ kg: 80 mg arthemeter + 480 mg lumefantirne 2/day for 3 days

2. Co-arinate (artesunate + sulfamethoxypyrazine + pyrimethamine)
5-14 kg: 50 mg artesunate+125mg sulfamethoxypyrazine+6.25mg pyrimethamine (t=0 and12 and 24 hrs later)

15-25 kg: 100 mg artesunate+250mg sulfamethoxypyrazine+12.5 mg pyrimethamine (t=0 and 12 and 24 hrs later)
25-34 kg: 150 mg artesunate+ 375 mg sulfamethoxypyrazine+ 18.75 mg pyrimethamine (t=0 and 12 and 24 hrs later)
35+ kg: 200 mg artesunate+500 mg sulfamethoxypyrazine+25 mg pyrimethamine (t=0 and 12 and 24 hrs later)

All drugs will be given orally. Follow-up of all participants will be at day 0, day 1, day 7, day 14, day 21, day 28, day 35 and day 42.

Intervention Type
Drug

Phase
Phase IV

Drug/device/biological/vaccine name(s)
Coartem, coarnate

Primary outcome measure
Parasite clearance as per WHO guidelines:
Full parasitological an clinical responses after 42 days of follow-up as measured by microscopy examination. At every follow-up visit a microscopy slide will be examined for parasites and counted against 200 whole blood count (WBC).

Secondary outcome measures
Gametocyte carriage:
At day 0,day 1, day 7 and day 14 blood samples (50 ul on filter paper) will be collected for molecular analysis of gametocytes. After nucleic acid extraction analysis will be done with NASBA and results will be expressed as gametocytes/ul

Overall study start date
15/09/2010

Completion date
30/06/2011

Eligibility

Key inclusion criteria
1. Either sex, age > 6 months
2. Simple malaria

Participant type(s)
Patient

Age group
Child

Lower age limit

6 Months

Sex
Not Specified

Target number of participants
900

Key exclusion criteria
Severe malaria

Date of first enrolment
15/09/2010

Date of final enrolment
30/06/2011

Locations

Countries of recruitment
Rwanda

Study participating centre
Kigali University Teaching Hospital
Kigali
Rwanda
655

Sponsor information

Organisation
INTERACT - Centre for Poverty related Communicable Diseases (CPCD) (Rwanda)

Sponsor details
Boulevard de la revolution
Kigali
Rwanda
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Sponsor type
Not defined

Funder(s)

Funder type
Research organisation

Funder Name
INTERACT (Rwanda)

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