

# Coartem or Coarnate for uncomplicated malaria and parasite carriage in Rwanda

<b>Submission date</b> 23/08/2010	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
<b>Registration date</b> 25/10/2010	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
<b>Last Edited</b> 25/10/2010	<b>Condition category</b> Infections and Infestations	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> 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 lumefantrine)**

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 lumefantrine 2/day for 3 days

**2. Co-arinate (artesunate + sulfamethoxypyrazine + pyrimethamine)**

5-14 kg: 50 mg artesunate+125mg sulfamethoxypyrazine+6.25mg pyrimethamine (t=0 and 12 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 and 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