

# Antimalarial drug quality in Gabon

No registrations found.

<b>Ethical review</b>	Not applicable
<b>Status</b>	Recruitment stopped
<b>Health condition type</b>	-
<b>Study type</b>	Observational non invasive

## Summary

### ID

NL-OMON20509

### Source

Nationaal Trial Register

### Brief title

AMQUAL

### Health condition

The quality of antimalarial drugs in the Gabonese Republic (Central Africa).

## Sponsors and support

**Primary sponsor:** Academic Medical Centre (AMC)

**Source(s) of monetary or material Support:** Academic Medical Centre (AMC)

## Intervention

## Outcome measures

### Primary outcome

- Quality of antimalarial drugs in Gabon.

### Secondary outcome

- Prevalence of poor quality antimalarial drugs.
- Proportion of outlets selling poor quality medicines.

- Prevalence/availability of antimalarial drugs that are no longer recommended as first or second line treatment in Gabon or by the World Health Organization (WHO).

If possible:

- Proportions of different types of poor quality medicines.

- Risk indicators of poor quality antimalarial drugs.

## Study description

### Background summary

Background: In Gabon, antimalarial drugs are widely available in both the private as well in the public sector and often self-prescribed (correctly and incorrectly) for the many febrile episodes attributed to malaria. Insufficient facilities to check the quality of antimalarial drugs, poor patient knowledge about these drugs; their relative high costs and the lack of appropriate regulatory and legal actions by the government make these drugs attractive for counterfeiters. Reports of poor quality and falsified drugs have increased in the past decade and evidence that a considerable proportion of drugs consumed in the developing world are of poor quality (often with no active or wrong ingredients) is emerging. Falsified drugs are an immediate threat for public health and have led to a great number of deaths from untreated malaria. For Gabon, there is no (published) data about the quality of available antimalarial drugs. We hypothesize that poor-quality anti-malarial drugs are prevalent in Gabon.

Objective: To describe the quality of available antimalarial drugs and to determine the prevalence of poor quality antimalarial drugs in Gabon. Most antimalarial drug samples will be collected in the province of Moyen-Ogooue.

Study design: (Non-clinical) - Prospective observational drug-quality field survey.

### Study objective

In Gabon, antimalarial drugs are widely available in both the private as well in the public sector and often self-prescribed (correctly and incorrectly) for the many febrile episodes attributed to malaria. Insufficient facilities to check the quality of antimalarial drugs, poor patient knowledge about these drugs; their relative high costs and the lack of appropriate regulatory and legal actions by the government make these drugs attractive for counterfeiters. Reports of poor quality and falsified drugs have increased in the past decade and evidence that a considerable proportion of drugs consumed in the developing world are of poor quality (often with no active or wrong ingredients) is emerging. Falsified drugs are an immediate threat for public health and have led to a great number of deaths from untreated malaria. For Gabon, there is no (published) data about the quality of available antimalarial drugs. We hypothesize that poor-quality anti-malarial drugs are prevalent in Gabon.

### Study design

20-30 December 2013: Pilot study

31 December 2013: Official start of study

24 January 2013: Total targeted sample size collected and transported to laboratory of AMC.

February 2013: Analysis of samples

March 2013: Preparing for publication to peer-reviewed medical journal

## **Intervention**

n/a

(This is a prospective observational drug-quality field survey)

## **Contacts**

### **Public**

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## **Eligibility criteria**

### **Inclusion criteria**

Antimalarial drugs that will be purchased, collected and analyzed are:

Amodiaquine; Artemether; Artesunate; Atovaquone; Chloroquine; dihydroartemisinin; Halofantrine; Lumefantrine; Mefloquine; Piperaquine; Primaquine; Proguanil; Pyrimethamine; Pyronaridine; Quinine; Sulfadoxine; Sulfamethoxypyrazine

## Exclusion criteria

n/a

## Study design

### Design

Study type:	Observational non invasive
Intervention model:	Other
Masking:	Double blinded (masking used)
Control:	N/A , unknown

### Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	31-12-2013
Enrollment:	400
Type:	Actual

## Ethics review

Not applicable	
Application type:	Not applicable

## Study registrations

### Followed up by the following (possibly more current) registration

No registrations found.

## Other (possibly less up-to-date) registrations in this register

No registrations found.

## In other registers

Register	ID
NTR-new	NL4191
NTR-old	NTR4341
Other	: 2013.11
ISRCTN	ISRCTN wordt niet meer aangevraagd.

## Study results

### Summary results

Assessing the quality of anti-malarial drugs from Gabonese pharmacies using the MiniLab ® : a field study

Benjamin J Visser, Janneke Meerveld-Gerrits, Daniëlle Kroon, Judith Mougoula, Rieke Vingerling, Emmanuel Bache, Jimmy Boersma, Michèle van Vugt, Selidji T Agnandji, Harparkash Kaur and Martin P Grobusch. Malaria Journal 2015, 14:273

doi:10.1186/s12936-015-0795-z

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The diagnostic accuracy of the hand-held Raman spectrometer for the identification of anti-malarial drugs. Benjamin J. Visser, Sophia G. de Vries, Emmanuel B. Bache, Janneke Meerveld-Gerrits, Daniëlle Kroon, Jimmy Boersma, Selidji T. Agnandji, Michèle van Vugt and Martin P. Grobusch. Malaria Journal 2016 15:160 DOI: 10.1186/s12936-016-1212-y