Antimalarial drug quality in Gabon

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Ethische beoordeling	Niet van toepassing
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON20509

Bron
NTR

Verkorte titel
AMQUAL

Aandoening

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

Ondersteuning

Primaire sponsor: Academic Medical Centre (AMC)
Overige ondersteuning: Academic Medical Centre (AMC)

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

- Quality of antimalarial drugs in Gabon.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

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

Onderzoeksproduct en/of interventie

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

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

n/a

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Anders
Blindering:	Dubbelblind
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	31-12-2013
Aantal proefpersonen:	400
Type:	Werkelijke startdatum

Ethische beoordeling

Niet van toepassing

Soort:	Niet van toepassing

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten

Samenvatting resultaten
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

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