Clinical evaluation of a magnetic device for the diagnosis of malaria.

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON23235

Source
NTR

Brief title
MOT

Health condition

Malaria

Sponsors and support

Primary sponsor: University of Exeter /royal tropical institute
Source(s) of monetary or material Support: europinion union

Intervention

Outcome measures

Primary outcome

- Positive or negative result for malaria

Secondary outcome

- Confounding effects of schistosomiasis haemozoin

Study description

Background summary

This clinical trial is designed to evaluate the performance of a novel Magneto-Optical Biosensors for Malaria Diagnosis [MOT-test; see Newman et al. 2008 Biophysical Journal 95: 394-399] under rural conditions in a disease endemic area in West Kenya (Mbita, Nyanza Province). MOT test performance will be compared to standard microscopical diagnosis of malaria (“gold standard”). Rapid diagnostic tests will be employed for quality control of microscopy. Patients, irrespective of age, with the clinical suspicion of uncomplicated malaria well be recruited for the study. Calculated study population size is 1500 people, with a malaria incidence between 15 – 20%. The study protocol was reviewed and approved by the Kenyan National Ethical Review Committee – Kenya Medical Research Institute (Nairobi, Kenya), under reference number NON-SSC084.

Study objective

The MOT test will be able to detect malaria parasites based on malarial pigment in a finger prick blood sample in less that a minute.

Study design

day 0

Intervention

Finger prick blood will be screened with the MOT device and compared to the outcome of standard microscopy.

Contacts

Public
Royal Tropical Institute
P. Mens
Meibergdreef 39
Amsterdam 1105 AZ
The Netherlands
+31 (0)20 5665467
Scientific
Royal Tropical Institute
P. Mens
Meibergdreef 39
Amsterdam 1105 AZ

The Netherlands
+31 (0)20 5665467

Eligibility criteria

Inclusion criteria

1. Clinical suspicion of uncomplicated malaria

2. T above 37.5 and below 39.5

3. Understanding the procedures and willing to participate

Exclusion criteria

1. Unwilling to participate and sign informed consent form

2. Not meeting the inclusion criteria

Study design

Design

Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	15-11-2008
Enrollment:	1300

Type:	Anticipated

Ethics review

Positive opinion Date:	12-11-2008
Application type:	First submission

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	NL1463
NTR-old	NTR1532
Other	European Commission, contract number : 016494
ISRCTN	ISRCTN wordt niet meer aangevraagd

Study results

Summary results
N/A