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Community-based scheduled screening and treatment of malaria in pregnancy for improved maternal and infant health

Submission date
22/05/2013

Recruitment status
No longer recruiting

Registration date
05/07/2013

Overall study status
Completed

Last Edited
03/04/2019

Condition category
Infections and Infestations

[X] Prospectively registered

[X] Protocol

[_] Statistical analysis plan

[X] Results

[_] Individual participant data

Plain English summary of protocol

Background and study aims
Malaria (a tropical disease spread by mosquitoes) is a common disease in Africa and is also a major health problem. Malaria in pregnancy is life threatening to both the mother and the baby. It can cause damage to the mothers blood and can result in babies being born with low birth weight, making them less healthy in their first years of life. These risks are even higher in women having their first child. When a woman is pregnant she should go to the antenatal clinic (ANC) for care. Usually the ANC health staff give her a drug (intermittent preventable treatment [IPTp-SP]) to protect against malaria. Each pregnant woman should receive at least two doses of this drug during their pregnancy. Therefore, they should go the ANC at least twice during their pregnancy. However, many women still do not go often enough to the ANC for health care during their pregnancy. This study aims to find out whether community health workers can work with pregnant women to encourage them to attend the ANC more often.

Who can participate?
Participants will be pregnant women aged 16 years or older who are living in the participating communities.

What does the study involve?
Villages will be randomly allocated to one of two groups. Pregnant women in one group will receive a protective drug against malaria and those in the other group receive standard care. The community health worker will test pregnant women every month for malaria. They will take some finger prick blood and use it for a rapid test. If a woman is found to have malaria, the community health worker will treat this woman in her home instead of her having to go to a health clinic. She will be treated with a different drug than the drug that is given at the ANC visits. We hope this will improve the care and management of malaria during pregnancy and improve the health of women and their newborn babies. To test this, we will take a small piece of the placenta (afterbirth) at delivery to test for malaria and also weigh the baby. We will test this method in multiple communities. We will compare this to pregnant women in communities where this method was not followed.

What are the possible benefits and risks of participating?
There are no direct benefits of participating in the study except that the outcome of our research may have possible health benefits in the group receiving the protective drug. The drugs involved are tested safe in pregnant women from the second trimester onwards.

Where is the study run from?
The study will be run in Benin (Atlantic Region in the southern part of the country, Glo-Djigbé, Zinvié and Zè district communities), Burkina Faso (the Nanoro health district catchment area, which is situated in the centre-west of Burkina Faso) and the Gambia (Basse Health Centre and satellite health facilities; villages situated in the southern and northern bank of the Upper River Region in the eastern part of the country).

When is the study starting and how long is it expected to run for?
The study will begin in September 2013 and is expected to run till March 2015.

Who is funding the study?
This study is funded by the European Commission (Belgium).

Who is the main contact?
Dr. Henk D. F. H. Schallig
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Study website
http://www.cosmicmalaria.eu/

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number
NCT01941264

Secondary identifying numbers
N/A

Study information

Scientific Title
COmmunity-based scheduled Screening and treatment of malaria in pregnancy for Improved maternal and infant health: a cluster-randomized trial in The Gambia, Burkina Faso and Benin

Acronym
COSMIC

Study objectives
Community-based scheduled screening and treatment of malaria in pregnancy in addition to intermittent preventive treatment in pregnancy will reduce the frequency of placental malaria in pregnant women compared to standard care.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Gambia Government/MRC laboratories Joint Ethics Committee, 25/06/2013, ref: SCC1336
2. Institutional Ethics Committee of Centre Muraz in Burkina Faso, 19/09/2013, ref A20-2013/CE-CM
3. Comite National dEthique pour la Recherché en Santé in Benin, 09/12/2013, No_0126/MS /DC /SGM /DFR /CNERS/SA

Study design
Multi-centre cluster randomized trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

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

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

Interventions

A two-armed cluster randomised controlled trial in which communities/villages will be randomised to receive either the intervention 'intermittent preventive treatment in pregnancy' plus 'community-based scheduled screening and treatment (IPTp-SP Plus CSST) or continue with the current treatment, i.e. intermittent preventive treatment with sulfadoxine-pyrimethamine (IPTp-SP) at health facilities when they attend antenatal clinics (ANCs).

Schedule of interventions:
In the intervention arm, women will be encouraged by community health workers to attend the ANC as early as possible during their pregnancy. Health staff will give the first IPTp-SP dose after the first trimester of pregnancy and plan the second dose on the ANC card. Between ANC visits community health workers (CHWs) will perform a monthly rapid diagnostic test (RDT) until the last weeks of gestation and treat any positive woman with artemether-lumefantrine (AL).

In the control arm, women will be recruited at the first ANC visit where staff will explain the study, give the first IPTp-SP dose after the first trimester of pregnancy and plan the second dose on the ANC card.

All women (in both arms) will be encouraged to deliver at health facilities, where a blood sample for haemoglobin measurement and for detection of malaria will be collected just before delivery. A placenta biopsy will be collected at delivery and the newborn examined and weighed. For women not delivering in a health centre, a field assistant (FA) will follow them up at home and will collect the same information and biological samples as at health facilities.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Placental malaria, at delivery a placental biopsy will be obtained that will be transferred to the Medical Research Council unit in the Gambia for histological analysis (presence of parasites and pigment deposition).

Secondary outcome measures
1. Maternal anaemia
2. Malaria peripheral infection
3. Low birth weight - newborns will be weighed as soon as possible after birth and gestational age will be established by the Ballard Score
4. IPTp-SP coverage by cluster (village/community), and selection of SP resistance markers
5. Antenatal clinic attendance and coverage of intermittent preventive treatment during pregnancy.

Overall study start date
01/09/2013

Completion date
01/03/2015

Eligibility

Key inclusion criteria
1. Residence in the study area and intention to stay in the area for the duration of the pregnancy and for delivery.
2. Aged at least 16 years (pregnant adolescents younger than 16 years will be considered only if they are accompanied by a responsible adult [in the Gambia] or married [considered an adult by marriage in Burkina Faso and Benin])
3. Willing to provide biological samples as and when required during the study period (blood and placental biopsy)
4. Informed consent

Participant type(s)
Patient

Age group
Adult

Sex
Female

Target number of participants
5400

Key exclusion criteria
1. A history of sensitivity to sulphonamides
2. Already participating in another research study

Date of first enrolment
01/09/2013

Date of final enrolment
01/03/2015

Locations

Countries of recruitment
Benin

Burkina Faso

Gambia

Netherlands

Study participating centre
Royal Tropical Institute (KIT)
Amsterdam
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Sponsor information

Organisation
Royal Tropical Institute (KIT)

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Sponsor type
Other

Website
http://www.kit.nl

ROR
https://ror.org/01z6bgg93

Funder(s)

Funder type
Government

Funder Name
European Commission (Belgium) - ref: FP7-HEALTH-2012-INNOVATION-1305662

Alternative Name(s)
European Union, Comisión Europea, Europäische Kommission, EU-Kommissionen, Euroopa Komisjoni, Ευρωπαϊκής Επιτροπής, Европейската комисия, Evropské komise, Commission européenne, Choimisiúin Eorpaigh, Europskoj komisiji, Commissione europea, La Commissione europea, Eiropas Komisiju, Europos Komisijos, Európai Bizottságról, Europese Commissie, Komisja Europejska, Comissão Europeia, Comisia Europeană, Európskej komisii, Evropski komisiji, Euroopan komission, Europeiska kommissionen, EC, EU

Funding Body Type
Government organisation

Funding Body Subtype

National government

Location

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	28/08/2014		Yes	No
Results article	results	02/11/2018		Yes	No
Results article	results	01/02/2019		Yes	No