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The effect of an enhanced antenatal care package for the control of malaria and anaemia in pregnancy in Ghana

Submission date
03/08/2015

Recruitment status
No longer recruiting

Registration date
20/08/2015

Overall study status
Completed

Last Edited
19/08/2015

Condition category
Pregnancy and Childbirth

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
In Ghana, there is a high rate of malaria and anaemia in pregnant women. These diseases contribute to the death and disease rates in mothers, and decrease the chance of survival in newborns. Educating people and encouraging them to become more involved in their own healthcare, has been found to lead to better health outcomes for both mother and child. This study aims to find whether encouraging pregnant women to be involved with their own healthcare during pregnancy will lead to lower levels of malaria and anaemia.

Who can participate?
Women not past their 32nd week of pregnancy, with at least 7g/dl haemoglobin present in a blood test.

What does the study involve?
Fourteen antenatal clinics in the Ejisu-Juaben Municipality and the Sekyere-East District of the Ashanti region of Ghana, are randomly allocated into either a control group or an intervention group (seven clinics per group). In addition to the standard care package, women attending clinics in the intervention group are tested for malaria and anaemia, and provided with extra healthcare advice in managing these conditions throughout their pregnancy. Women in the control group are not provided with these extra tests.
The levels of malaria and anaemia are then re-tested after 4-8 weeks in all participants to see whether the extra care helps to lower the incidence of these conditions.

What are the possible benefits and risks of participating?
Benefits of participating in the study include the women being able to have their haemoglobin levels checked. Those in the intervention group also have the benefit of being able to see their test results from the use of the haemoglobin colour scale and the rapid diagnostic test (RDT) as they participated in their care. If these women test positive for malaria, then they would also be able to receive treatment. There are no major risks of participating, pricking of the finger tips at each antenatal care visit for the blood tests could cause some pain and/or discomfort to the women as well as the risk of infection that goes with blood tests.

Where is the study run from?
The Ejisu-Juaben Municipality and the Sekyere-East District of the Ashanti region of Ghana

When is the study starting and how long is it expected to run for?
December 2011 to April 2014

Who is funding the study?
Malaria Capacity Development Consortium, London School of Hygiene and Tropical Medicine (UK)

Who is the main contact?
Dr Gifty Antwi

Contact information

Type(s)
Scientific

Contact name
Dr Gifty Antwi

Contact details
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
A cluster randomised controlled trial of an Enhanced AnteNatal Care service package for the control of Malaria and Anaemia in Pregnancy

Acronym
EANC-MAP

Study objectives

When pregnant women participate in their antenatal care through the use of the rapid diagnostic test and the haemoglobin colour scale as point-of-care tests for the diagnosis of malaria and anaemia, it will improve their adherence to antenatal care recommendations and treatments with regards to malaria and anaemia and thus improve maternal and pregnancy outcomes.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Committee on Human Research, Publications and Ethics (CHRPE) of the Kwame Nkrumah University of Science and Technology, 19/12/2011, CHRPE/AP/105/11.

Study design
Interventional cluster randomised controlled trial

Primary study design
Interventional

Secondary study design
Cluster randomised trial

Study setting(s)
Other

Study type(s)
Other

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
1. Malaria
2. Anaemia

Interventions
Control: Women in the control group will be provided with the current antenatal care package which includes: The taking of medical and obstetric history; measuring blood pressure, weight, height and temperature; measurement of symphysio-fundal height and foetal viability; routine urine and stool examinations, blood grouping, sickling test, VDRL for syphilis and HIV testing; screening for malaria and anaemia at the first antenatal visit and at for anaemia at 36 weeks gestation; giving intermittent preventive treatment for malaria and tetanus toxoid injections; folic acid and iron supplementation, presumptive de-worming, education on insecticide treated net use, dietary advice and scheduling of next antenatal care visits.

Intervention: In addition to receiving the current antenatal care package, women in the intervention group will participate in their antenatal care through the use of the simple, easy to interpret, visually appealing point-of-care tests: the rapid diagnostic test (RDT) for malaria and

the haemoglobin colour scale (HCS) for anaemia.
The antenatal care staff will conduct the tests with the pregnant women, who are allowed to see their results during their antenatal care sessions.

Intervention Type
Behavioural

Primary outcome measure
1. Prevalence of malaria parasitaemia at 4-8 weeks after enrollment
2. Prevalence of anaemia 4-8 weeks after enrollment

Secondary outcome measures
1. Prevalence of malaria parasitaemia prior to delivery
2. Prevalence of anaemia prior to delivery
3. Prevalence of low birth weight
4. Prevalence of sub-optimal pregnancy outcomes (still births, abortions, miscarriages)
5. Level of pregnant women's knowledge about malaria and anaemia in pregnancy
6. Level of pregnant women's adherence to health advice
7. Feasibility and acceptability of the use of HCS and RDT during antenatal care

Overall study start date
21/12/2011

Completion date
30/04/2014

Eligibility

Key inclusion criteria
1. Pregnant woman visiting the antenatal clinic for the first time for the current pregnancy
2. Up to 32 weeks gestation at booking
3. Haermoglobin ≥ 7g/dl at booking
4. Within the catchment area of the health facility

Participant type(s)
Patient

Age group
Adult

Sex
Female

Target number of participants
14 clusters, 7 clusters per arm, with a minimum of 84 pregnant women per cluster. In all 1663 pregnant women were recruited.

Key exclusion criteria
1. Pregnant woman with a history or presence of any systemic illness likely to interfere with interpretation of trial results e.g. HIV-AIDS, sickle cell disease, G-6PD deficiency

2. Pregnant woman with any significant illness at time of screening that required hospitalization (including severe anaemia)

Date of first enrolment
01/09/2012

Date of final enrolment
31/12/2013

Locations

Countries of recruitment
Ghana

Study participating centre
Sekyere-East District of the Ashanti region of Ghana
Effiduase
Ghana
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Study participating centre
Ejisu-Juaben Municipality of the Ashanti Region of Ghana
Ejisu
Ghana
-

Sponsor information

Organisation
Department of Global and International Health

Sponsor details
School of Public Health
Kwame Nkrumah University of Science and Technology
Kumasi
Ghana
-

Sponsor type
University/education

ROR
https://ror.org/00cb23x68

Funder(s)

Funder type
University/education

Funder Name
Malaria Capacity Development Consortium, London School of Hygiene and Tropical Medicine (UK)

Results and Publications

Publication and dissemination plan
1. The effect of an enhanced antenatal care service package on malaria and anaemia during pregnancy in Ghana to be published in a peer reviewed journal latest by March, 2016.
2. Feasibility and acceptability of the use of the haemoglobin colour scale and the rapid diagnostic test for malaria during antenatal care sessions in Ghana to be published in a peer reviewed journal latest by March, 2016.
3. Dissemination of study results with members of the Ejisu-Juaben Municipality and the Sekyere-East District health management teams and antenatal care staff members of these two areas by December, 2015.

Intention to publish date
01/03/2016

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration