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Combining health services for malaria and maternal and child health to improve health of mothers and children in rural communities

Submission date
09/01/2017

Recruitment status
No longer recruiting

Registration date
27/02/2017

Overall study status
Completed

Last Edited
05/04/2019

Condition category
Infections and Infestations

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

Plain English summary of protocol

Background and study aims
Malaria is a tropical infection that is spread through mosquitoes. Malaria can be very serious and even fatal as it only takes one mosquito bite to become infected. The symptoms include fever (a high temperature), sweats and chills, vomiting, pain, diarrhoea and headache. Malaria can be prevented and treated by taking antimalarial medication. Cambodia has a very high rate of malaria and therefore has increased the number of Village Malaria Workers (VMWs; community based workers trained to provide treatment for malaria). Despite this, the rates of malaria have still remained high Pregnant women in Cambodia are very vulnerable to malaria and they rarely get in depth care throughout their pregnancy, during birth, and after delivery. Combining both malaria treatments and maternal, neonatal, and child health (MNCH) services could help lower malaria rates and improve the health of women and babies, improving health systems in Cambodia. The aim of this study is to see if combining malaria control and MNCH services can improve the healthcare of women in Cambodia and reduce malaria rates.

Who can participate?
Women who are between the ages of 18 and 29 that are pregnant or have children under the age of two years old living in the participating villages.

What does the study involve?
Participating villages are allocated to one of two groups. Those in the first group receive the integrated continuum of care (ICoC) program through Village Malaria Workers (VMWs) that includes regular health check-ups, health education, and being set up on a system that guides and tracks patients. The second group receive care from VMWs and then are enrolled in the same ICoC program of the first group if there is a positive impact. Two years after the program, follow up is done by randomly surveying participants to ask about their health behaviours and knowledge of maternal health.

What are the possible benefits and risks of participating?
Participants may benefit from increased knowledge about malaria and maternal health. Health centers will have and VMW will benefit from receiving new equipment that will help them diagnose and treat malaria. There are no direct risks of participating.

Where is the study run from?
This trial is run from the University of Tokyo (Japan) and takes place in six health centers in the Ratanakiri province (Cambodia)

When is the study starting and how long is it expected to run for?
April 2015 to March 2020

Who is funding the study?
Japanese Society for the Promotion of Science (Japan)

Who is the main contact?
Dr Junko Yasuoka

Contact information

Type(s)
Scientific

Contact name
Dr Junko Yasuoka

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Integration of malaria control activities and Maternal, Neonatal, and Child Health services to achieve malaria elimination and better maternal and child health

Acronym
MNCH

Study objectives
Integration of malaria control and MNCH services through village malaria workers (VMWs') network can promote active case detection and treatment of malaria for pregnant women and improve MNCH Integrated Continuum of Care (ICoC).

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Research Ethics Committee of the Graduate School of Medicine The University of Tokyo, 11/30 /2015, ref: 11030
2. National Ethical Committee for Health Research Cambodia, 10/31/2016, ref: 368NECHR

Study design
Non-randomised controlled trial

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Community

Study type(s)
Prevention

Participant information sheet

Health condition(s) or problem(s) studied
Malaria and Maternal, Neonatal, and Child Health

Interventions
Participants are allocated into two study arms: the intervention arm and the control arm. Out of 62 Village Malaria Worker villages under six health centers, which are accessible throughout the year in Ratanakiri province, 30 villages under three health centers will be selected by convenience sampling.

The intervention arm involves 30 villages with Village Malaria Workers (VMWs) in Ratanakiri and will include the following:
1. Integrated Continuum of Care (ICoC) orientation
2. ICoC card utilization
3. Regular malaria test and health check-ups
4. Health education

The control arm involves 32 VMW villages and they receive standard care.

After two years from the initiation of the intervention, follow-up survey (face-to-face interviews using structured questionnaire) will be conducted, targeting
- Participants of the intervention in intervention villages
- Randomly selected mothers with children under two in control villages
The follow-up survey will ask about mothers' knowledge and health behavior during and after pregnancy.

Intervention Type
Behavioural

Primary outcome measure
1. Percentage of pregnant women who receive malaria test measured using the Rapid Diagnostic Test four times during pregnancy (about 4 months, 6-7 months, 8 months, and 9 months)
2. Percentage of mothers, who receive all three maternal, neonatal, and child health (MHCH) services (antenatal care, delivery and postnatal care) or Village Malaria Workers' health check-up four times during pregnancy and after delivery is measured using the integrated continuum care (ICoC) card and is done four times during antenatal care (about 4 months, 6-7 months, 8 months, and 9 months), at delivery, and three times for postnatal care (by 2 days, at 7 days, and at 6 weeks)

Secondary outcome measures
1. Pregnant women's and mothers' knowledge about danger signs, breastfeeding, and proper feeding practices for children under two is measured using face to face interviews using structured questionnaires at the end of the intervention
2. Rate of infectious diseases, including malaria, diarrhea, and pneumonia, among mothers and children under two is measured using records in the ICoC at the end of the intervention

Overall study start date
01/04/2015

Completion date
31/03/2020

Eligibility

Key inclusion criteria
Intervention arm:
1. Pregnant women
1.2. Between the ages of 18 and 49 years old (reproductive age)
2. Mothers with children under two

Control arm:
1. Pregnant women
1.2. Between the ages 18 and 49 years old (reproductive age)
2. Mothers with children under two

Participant type(s)
Mixed

Age group

Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
400

Total final enrolment
696

Key exclusion criteria
1. Refused participating with the intervention
2. Decline to be interviewed

Date of first enrolment
01/03/2017

Date of final enrolment
01/03/2019

Locations

Countries of recruitment
Cambodia

Japan

Study participating centre
The University of Tokyo, Japan (lead centre) and six
7-3-1 Hongo
Bunkyo-ku
Tokyo
Japan
113-0033

Study participating centre
National Center for Parasitology, Entomology and Malaria Control Cambodia
Corner street 92
Trapaing Svay Village
Sankat Phnom Penh Thmey
Khan Sensok

Phnom Penh
Cambodia
N\A

Study participating centre
Kyushu University
Institute of Decision Science for a Sustainable Society
Motooka
Nishi Ward
Fukuoka prefecture
Fukoka
Japan
819-0385

Sponsor information

Organisation
Japanese Society for the Promotion of Science (Grant-in-Aid for Scientific Research)

Sponsor details
Kojimachi Business Center Building
5-3-1 Kojimachi, Chiyoda-ku
Tokyo
Japan
102-0083

Sponsor type
Research council

ROR
https://ror.org/00hhkn466

Funder(s)

Funder type
Research organisation

Funder Name
Japanese Society for the Promotion of Science (Grant-in-Aid for Scientific Research)

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer reviewed journal.

Intention to publish date
29/02/2020

Individual participant data (IPD) sharing plan
The current data sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary
Data sharing statement to be made available at a later date