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PANDA mHealth system for antenatal care

Submission date
18/09/2015

Recruitment status
No longer recruiting

Registration date
14/10/2015

Overall study status
Completed

Last Edited
30/10/2020

Condition category
Pregnancy and Childbirth

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

Plain English Summary

Background and study aims
Madagascar has a high rate of deaths among women giving birth. It has been shown that giving birth with the help of a skilled birth attendant, such as a doctor or midwife, can reduce the risk of complications, such as excessive bleeding (haemorrhage) that lead to death of mothers and their newborn babies. In Madagascar, only 44% of women give birth in the presence of a skilled birth attendant and so many women do not have access to life saving treatment. mHealth is a system which uses mobile technology, such as mobile phones or personal digital assistants (PDAs) to support healthcare. The pregnancy and newborn diagnostic assessment (PANDA) system is a mHealth system which has been specifically designed for community-Health Workers (CHWs) to reach pregnant women in remote areas. It allows them to carry out screening, collect information and provide education about healthcare. The aim of this study is to evaluate how effective the PANDA system is for providing antenatal care to women in remote areas.

Who can participate?
Pregnant women living in Madagascar.

What does the study involve?
Women attend an antenatal care visit and their medical history is taken by a healthcare worker. This information is then linked to a random ID number for each woman. At this visit, the women also are tested for HIV, syphilis and malaria, as well as having standard measurements taken to assess their general health. If any women have abnormal results to these tests, their results are sent to them immediately by smartphone and they receive a follow up appointment at the local hospital. For the rest of the study, test results and information are sent to the medical centre everyday via smartphone so that they are away of any potential risks during the pregnancy and can intervene if necessary.

What are the possible benefits and risks of participating?
The main benefits of taking part in the study are that the women involved will have access to high quality antenatal care, including screening for diseases. There are no risks of taking part in the study.

Where is the study run from?
Centre Médico Chirurgical Saint Damien (Madagascar)

When is the study starting and how long is it expected to run for?
January 2015 to October 2015

Who is funding the study?
1. Commission of Humanitarian Affairs, Geneva (Switzerland)
2. Romand Group of the Swiss Society of Gynecology (Switzerland)
3. Valdese Church (Italy)

Who is the main contact?
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Contact information

Type(s)
Public

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Usability and feasibility of a mobile health system to provide comprehensive antenatal care in low-income countries: PANDA mHealth pilot study in Madagascar

Acronym
PANDA

Study hypothesis
To assess the usability and feasibility of a mobile health system (mHealth) to provide high quality antenatal care according to World Health Organization (WHO) recommendations.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Ethical Cantonal Board of Geneva (Commission cantonale d'éthique et de la recherche), 12/01/2015, ref: CER 14-217
2. Ethical Committee of Madagascar (Comite national d'êthique de Madagascar), 12/01/2015

Study design
Cross-sectional pilot feasibility study

Primary study design
Observational

Secondary study design
Cross sectional study

Study setting(s)
Other

Study type(s)
Prevention

Participant information sheet

Condition
Most maternal and newborn deaths are related to direct complications during pregnancy and childbirth and could be reduced by providing comprehensive antenatal care

Interventions
The women enrolled will attend a number of ANC visits along the pregancy according with WHO recomandations and the stage of pregnancy at the time of the enrollment. A random ID number will be assigned to each women, to which their clinical data and test results will be linked. ANC visits will start with the collection of social/personal data and medical history and then screening tests (HIV, HPV syphilis, malaria, haemoglobin, glucose) as well as other measurements (temperature, weight, height, blood pressure, uterine height) will be conducted. All results will be available at the end of the visits except for the HPV where the self-sampling of the women will be collected and sent to the virology laboratory in Geneva and destroyed after one year. Abnormal results will be signalised immediately by the smartphone and the woman will be referred to the hospital. Once the screening is completed, the PANDA team will proceed to health education, focusing on maternal and newborn care and birth preparedness as well as family planning. On a daily basis, data and test results will be sent via the mobile phone to the medical unit, for data verification and personalised intervention plans in order to optimise the management of pregnancies and childbirths, and to ensure appropriate care for high risk pregnancies.

Intervention Type
Other

Primary outcome measure
PANDA system feasibility using the Redmine tool an open source flexible project management web application with a ticket tracking system collecting all the items in real time during the ANC visits.

Secondary outcome measures
1. The capacity of PANDA system to provide standardised and high quality ANC, measured using the percentage of missing data and deviations from the WHO guidelines of the ANC visits. Data verification done at the end of each day of antenatal visits
2. The capacity of the system to map the pregnancies in order to help health personnel for a better management of the resources, measured using the number of women referred to the hospital for treatment and follow-up. Data is verified daily by the hospital obstetric team

Overall study start date
13/01/2015

Overall study end date
30/10/2015

Eligibility

Participant inclusion criteria
1. Pregnant women

Participant type(s)
Patient

Age group
All

Sex
Female

Target number of participants
300 pregnant women

Total final enrolment
1015

Participant exclusion criteria
Patients who are not able to comply with the protocol

Recruitment start date
13/01/2015

Recruitment end date
01/08/2018

Locations

Countries of recruitment
Madagascar

Study participating centre
Centre Médico Chirurgical Saint Damien
Ambanja
Madagascar
103

Sponsor information

Organisation
Hôpitaux Universitaires de Genève

Sponsor details
Boulevard de la Cluse 30
Geneva
Switzerland
1205

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/01m1pv723

Funder(s)

Funder type
Government

Funder Name
Commission of Humanitarian Affairs, Geneva

Funder Name
Romand Group of the Swiss Society of Gynecology

Funder Name
Valdese Church

Results and Publications

Publication and dissemination plan
September 2015: submission for publication regarding usability and feasibility test regarding the first 100 patients
November 2015: Oral presentation at the "Congrès du Groupement Romand de la Société Suisse de Gynécologie"
January 2016: submission for publication for the results of 300 patients

Intention to publish date
31/01/2016

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	12/10/2020	30/10/2020	Yes	No