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Maternal and perinatal outcomes after caesarean section in Sierra Leone

Submission date
24/09/2016

Recruitment status
No longer recruiting

Registration date
13/10/2016

Overall study status
Completed

Last Edited
05/11/2024

Condition category
Pregnancy and Childbirth

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

Plain English summary of protocol

Background and study aims
Every year, one and a half million deaths can be avoided if safe essential and emergency surgical care is available. Shortage of health care staff is considered the main reason for the extensive unmet need for surgery. Sierra Leone has one of the highest maternal mortality ratios in the world, with 11 mothers dying of pregnancy-related complications for every 1000 live born babies. Access to affordable and quality surgical services is limited. One possibility to improve access to essential obstetric and surgical care is to train non-physician clinicians (NPCs). Since 2011, NPCs have been trained to perform essential obstetric and surgical care, based upon the example from East Africa. To date, there are few studies that have examined the safety of surgical task-sharing. The aim of this study is to assess the quality of surgical care in Sierra Leone and examine differences in morbidity (disease) and mortality (deaths) after caesarean sections performed by medical doctors and NPCs.

Who can participate?
Women who undergo a caesarean section in hospitals where both medical doctors and NPCs are working

What does the study involve?
Information is collected during and after the caesarean section operation, at discharge and during home visits after 30 days, 1 year and 5 years. During these visits, the research nurse checks the mother's wound, does a simple examination of the baby, and collects data on following pregnancies and health expenditure.

What are the possible benefits and risks of participating?
Participants receive an incentive in the form of a health promotion package during the home visits. The study will not delay or interfere with treatment. There are no specific risks related to participation in this study.

Where is the study run from?
The study is organized by the Norwegian University of Science and Technology, Trondheim (Norway) in cooperation with the Ministry of Health and Sanitation of Sierra Leone. Other partners: Lund University (Sweden), King's College London (UK), College of Medicine and Allied

Health Sciences, Freetown (Sierra Leone), United Nations Population Fund, Freetown (Sierra Leone).

When is the study starting and how long is it expected to run for?
October 2016 to October 2022

Who is funding the study?
The study is funded by Liaison Committee between the Central Norway Regional Health Authority (RHA) and the Norwegian University of Science and Technology (NTNU) with additional support from United Nations Population Fund.

Who is the main contact?
Alex van Duinen, aalke.j.v.duinen@ntnu.no

Contact information

Type(s)
Scientific

Contact name
Mr Alex van Duinen

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Masanga Hospital
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N/A

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
1

Study information

Scientific Title
Maternal and perinatal outcomes after caesarean section performed by medical doctors and non-physician clinicians in Sierra Leone: a prospective observational study

Study objectives
The outcome after cesarean section performed by non-physician clinicians is not inferior compared to cesarean sections performed by medical doctors.

Ethics approval required

Old ethics approval format

Ethics approval(s)
1. Office of the Sierra Leone Ethics and Scientific Review Committee, 19/05/2016
2. Norwegian Regional Central Committee for Medical and Health Research Ethics, 08/09/2016, ref: 2016/1163/REK Midt

Study design
Multicentre prospective observational study

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
Hospital

Study type(s)
Treatment

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

Health condition(s) or problem(s) studied
Caesarean section or laparotomy for uterus rupture

Interventions
Inclusion and first data collection will be done by trained anaesthesia team members which are working in the study facilities. Data collected during the first data collection is categorized in: informed consent, inclusion/exclusion criteria, patient details, pregnancy-related information and obstetric history, onset of labour, perioperative information.

Routinely, the research nurse will visit the hospital to collect and confirm the data and will add discharge data. After confirmation, the data are sent to the central collection point. After entering the data into the database follow-up visits are planned after 30 days (with a window period of +14 days), 1 year and 5 years. During these visits, the research nurse will collect data on maternal and perinatal outcome, following pregnancies, health expenditure and socioeconomic status. The research nurse will check the wound of the mother and do a simple examination of the baby.

Intervention Type
Other

Primary outcome measure
Maternal and neonatal survival, measured by research nurse before discharge and at 30-day follow-up visit

Secondary outcome measures

1. Infection, including wound infection, treated with antibiotics before discharge
2. Reoperation for wound dehiscence before discharge
3. New pregnancy within the first year
4. Development of vesicovaginal fistula (VVF) within the first year
5. Uterus rupture within 5 years after caesarean section
All outcomes measured by research nurse at discharge and follow-up visits

Overall study start date
01/10/2016

Completion date
01/10/2022

Eligibility

Key inclusion criteria
1. Pregnant women who undergo a caesarean section (including laparotomy for uterine rupture)
2. The foetus is over 500 grams
3. The procedure is performed by a Medical Doctor or a Non-Physician Clinician

Participant type(s)
Patient

Age group
Adult

Sex
Female

Target number of participants
1200

Key exclusion criteria
1. Caesarean section performed by a student (for example medical student) as first surgeon
2. Patients who have undergone laparotomy for uterine rupture where the foetus is already delivered vaginally

Date of first enrolment
01/10/2016

Date of final enrolment
06/05/2017

Locations

Countries of recruitment
Sierra Leone

Study participating centre
Lion Heart Medical Center
Yele
Sierra Leone
-

Study participating centre
Magbenteh Community Hospital
Makeni
Sierra Leone
-

Study participating centre
Serabu Mission Hospital
Serabu
Sierra Leone
-

Study participating centre
Magburaka Governmental Hospital
Magburaka
Sierra Leone
-

Study participating centre
Princess Christian Maternity Hospital (PCMH)
Freetown
Sierra Leone
-

Study participating centre
Kabala Governmental Hospital
Kabala
Sierra Leone
-

Study participating centre
Kenema Governmental Hospital
Kenema

Sierra Leone
-

Study participating centre
Kambia Governmental Hospital
Kambia
Sierra Leone
-

Study participating centre
Port Loko Governmental Hospital
Port Loko
Sierra Leone
-

Sponsor information

Organisation
Institute of Cancer Research and Molecular Medicine of the Norwegian University of Science and Technology

Sponsor details
Olav Kyrres gt 9
Trondheim
Norway
N-7491

Sponsor type
University/education

Website
http://www.ntnu.no/dmf/

ROR
https://ror.org/05xg72x27

Funder(s)

Funder type
Other

Funder Name
Liaison Committee between the Central Norway Regional Health Authority and the Norwegian University of Science and Technology

Results and Publications

Publication and dissemination plan
The results of the study will be published in international peer-reviewed journals and at national and international conferences. The aim is to have the first results and research protocol published within one year after finalizing the data collection.

Intention to publish date
01/10/2023

Individual participant data (IPD) sharing plan
The datasets generated and/or analysed during the current study are available from Alex van Duinen on reasonable request, aalke.j.v.duinen@ntnu.no.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		01/12/2020	05/11/2024	Yes	No
Results article		01/01/2019	05/11/2024	Yes	No