

Maternal and perinatal outcomes after caesarean section in Sierra Leone

Submission date 24/09/2016	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 13/10/2016	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
Last Edited 05/11/2024	Condition category Pregnancy and Childbirth	<input type="checkbox"/> 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

Contact details

Masanga Hospital
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Sierra Leone
N/A

Additional identifiers

Protocol serial number

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

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Adult

Sex

Female

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

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

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