

# Maternal and perinatal outcomes after caesarean section in Sierra Leone

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

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**Study participating centre**  
**Magbenteh Community Hospital**  
Makeni  
Sierra Leone

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**Study participating centre**  
**Serabu Mission Hospital**  
Serabu  
Sierra Leone

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**Study participating centre**  
**Magburaka Governmental Hospital**  
Magburaka  
Sierra Leone

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

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**Study participating centre**  
**Kabala Governmental Hospital**  
Kabala  
Sierra Leone

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**Study participating centre**  
**Kenema Governmental Hospital**  
Kenema

Sierra Leone

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**Study participating centre**

**Kambia Governmental Hospital**

Kambia

Sierra Leone

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**Study participating centre**

**Port Loko Governmental Hospital**

Port Loko

Sierra Leone

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## **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](mailto: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?
<a href="#">Results article</a>		01/12/2020	05/11/2024	Yes	No
<a href="#">Results article</a>		01/01/2019	05/11/2024	Yes	No