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Maternal and neonatal outcomes in placenta previa deliveries

Submission date	Recruitment status	[X] Prospectively registered
26/03/2019	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
28/03/2019	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
09/12/2019	Pregnancy and Childbirth	[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Placenta previa is a condition where the placenta lies low in the uterus (womb) and partially or completely covers the cervix.. It is associated with numerous complications, such as perinatal hemorrhage (bleeding), preterm birth, blood transfusion, hysterectomy (removal of the womb), intensive care unit admission, disseminated intravascular coagulation, septicemia (blood poisoning), thrombophlebitis (blood clots), and even death. Cesarean delivery and assisted reproductive technology are associated with an increased risk of placenta previa in subsequent pregnancies. Other risk factors for previa include previous spontaneous, elective pregnancy terminations, previous uterine surgery, increasing maternal age and maternal parity, multiple gestations, smoking, cocaine use, and prior previa. The aim of this study is to investigate outcomes for pregnant women with placenta previa.

Who can participate?
Pregnant women diagnosed with placenta previa after delivery

What does the study involve?
Outcomes data is taken from electronic databases of findings collected as part of routine clinical care.

What are the possible benefits and risks of participating?
The possible benefits of this study are that eventually researchers may improve outcomes for pregnant women with placenta previa. No burdens or risks for participants are expected as the study is purely observational.

Where is the study run from?
The Southern Medical University Affiliated Maternal & Child Health Hospital of Foshan, Foshan, China

When is the study starting and how long is it expected to run for?
February 2019 to January 2021 (updated 09/12/2019, previously: January 2020)

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
Prof. Zhengping Liu
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Contact information

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Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
Nil known

Study information

Scientific Title
Maternal and neonatal outcomes in placenta previa deliveries: a retrospective case-control study

Study objectives
Placenta previa can increase the risk of maternal and neonatal outcomes.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 16/05/2019, Medical Ethics Committee of Southern Medical University Affiliated Maternal & Child Health Hospital of Foshan (11 Renminxi Road, Foshan, Guangdong, 528000, China; Tel: +86 757 82969878; Email: trials_fs_mchh@sohu.com), ref: FSFY-20190201

Study design
Single-center retrospective hospital-based case-control study

Primary study design
Observational

Study type(s)
Other

Health condition(s) or problem(s) studied
Placenta previa deliveries

Interventions
This is a single-center, retrospective, and hospital-based case-control study with one-year follow-up to investigate maternal and neonatal outcomes in pregnant women with placenta previa. For each woman with placenta previa, the investigators selected two non-placenta previa pregnant women as controls from the same department matched on the mode of delivery, using simple random selection when excess matches are available.

Intervention Type
Other

Primary outcome(s)
Number of participants with postpartum hemorrhage during cesarean section or vaginal delivery. The estimated blood loss is measured 24 hours after delivery by summing the amount of blood absorbed by medical gauze and the blood in the suction unit. If the total amount of blood loss in excess of 1000 ml during cesarean section or 500 ml during vaginal delivery, it is defined as post-partum hemorrhage.

Key secondary outcome(s))

1. Birth weight of the newborn is directly measured by nurses using electronic scales after delivery
2. Apgar score at 1 and 5 minutes is directly made by nurses according to Apgar scale at 1 and 5 minutes after delivery, respectively
3. Gestational age at delivery is determined on the basis of the last menstrual period and confirmed by an ultrasound scan taken between the 14th and 20th week
4. Number of participants with postpartum hysterectomy. If the uterus is removed after delivery due to childbirth, it is defined as postpartum hysterectomy

Completion date
31/01/2021

Eligibility

Key inclusion criteria
Pregnant women diagnosed with placenta previa after delivery. Placenta previa is diagnosed by experienced ultrasonologists based on a transabdominal ultrasonic finding of placental tissue covering the internal cervical os before delivery, and further confirmed by obstetricians at delivery.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
Female

Key exclusion criteria
Before 28 completed gestational weeks

Date of first enrolment
01/05/2019

Date of final enrolment
30/11/2020

Locations

Countries of recruitment
China

Study participating centre

Southern Medical University Affiliated Maternal & Child Health Hospital of Foshan
11 Renminxi Road
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Sponsor information

Organisation
Southern Medical University Affiliated Maternal & Child Health Hospital of Foshan

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan
Prof. Zhengping Liu (liuzphlk81@outlook.com) or Dr Dazhi Fan (fandazhigw@163.com) should be contacted for access to the datasets after the trial.

IPD sharing plan summary
Available on request