ISRCTN15181117 https://doi.org/10.1186/ISRCTN15181117

The effect of anesthetic technique on neonatal morbidity in emergent cesarean section for fetal distress

Submission date
12/12/2015

Recruitment status
No longer recruiting

Registration date
15/02/2016

Overall study status
Completed

Last Edited
10/03/2023

Condition category
Pregnancy and Childbirth

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

Plain English summary of protocol

Background and study aims
An emergent (or emergency) caesarean section is one of the biggest challenges faced by an obstetric anaesthetist. As the outcome for both mother and unborn baby depends on the coordination and vigilance of the obstetrician and anaesthetist, the decision on what anesthetic technique to use can be of paramount importance. Current guidelines suggest regional (local) anaesthesia should be given in preference to general anaesthesia for elective (pre-planned) caesarean sections. However, for an emergency caesarean section, there may not be enough time to give a regional anaesthetic. Evidence does suggest that regional anaesthesia should be chosen in preference to general anaesthesia if there is time. However, there are few published studies looking at the neonatal morbidity (disease causing) for emergency caesareans where the baby has been identified as being in distress (foetal distress). In this study, neonatal morbidity will be compared for emergency caesarean sections carried out using regional anaesthesia compared with general anaesthesia.

Who can participate?
Women aged 18-45 in labour where their unborn baby is showing signs of distress.

What does the study involve?
For each patient in the study, the senior anaesthetist decides the type of anaesthesia according to both national guidelines and patients' approval. The patients are divided into two groups, general anaesthesia group (group g) or regional anaesthesia group (group r). Heart rate, arterial tension pressure and demographic data are all recorded for each patient. Once the baby is born, APGAR scores (a way of summarising the health of a newborn baby) are recorded one minute after birth and then again at 3 minutes and 5 minutes after birth. If the babies condition is critical and there are umbilical blood gases (suggesting foetal distress) this data is also recorded. After the operation , the neonates are followed up until their discharge from hospital. Any morbid (disease-causing) conditions are also recorded.

What are the possible benefits and risks of participating?
There is no risk for the participants because it is an observational study.

Where is the study run from?
Suleymaniye Birth and Women's Health Education and Research Hospital, Istanbul (Turkey)

When is the study starting and how long is it expected to run for?
July 2015 to December 2015

Who is funding the study?
Suleymaniye Birth and Women's Health Education and Research Hospital, Istanbul (Turkey)

Who is the main contact?
Dr Ipek Saadet Edipoglu

Contact information

Type(s)
Scientific

Contact name
Dr Ipek Saadet Edipoglu

Contact details
Suleymaniye Birth And Women's Health Education And Research Hospital
Telsiz Mah. Balıklı Kazlıcesme Yolu No:1 Zeytinburnu
Istanbul
Türkiye
34116

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
The effect of anaesthetic technique on neonatal morbidity in emergent caesarean section for fetal distress: a prospective observational study

Study objectives
To investigate the effect of anesthetic technique on neonatal morbidity in emergent cesareans by observing if administering regional anesthesia or general anesthesia influences the morbidity of the neonate.

Ethics approval required

Old ethics approval format

Ethics approval(s)
Research Hospital Clinical Studies Ethical Committee, 29/06/2015, ref: 2015/127

Study design
Single centered 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 contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Fetal distress and anesthetic technique

Interventions
We are going to observe emergent cesarean sections which are diagnosed as fetal distress. We are not going to intervene regarding the patients anesthetic choice. Regional anesthesia or general anesthesia will be applied according to the patients indication. The consultant anesthesiologist makes the decision about the type of anesthesia for emergent cesarean sections according to our national guidelines in our hospital. We are just going to observe and divide them into two groups: general anesthesia group and regional anesthesia group. The following will be recorded in all cases:
1. All patients peri-operative heart rate and mean arterial pressures
2. All neonates APGAR scores at 1, 3 and 5 minutes
3. The need for mechanical ventilation will also be recorded.
4. All morbid conditions

Intervention Type
Procedure/Surgery

Primary outcome measure
Neonatal morbidity, measured with APGAR scores in 1st, 3rd, 5th minutes, and umbilical blood gas (if indicated). After the operation we will follow neonates until discharge and record any morbid conditions. We define morbidity as 5-minute Apgar score (APGAR5) <7, any need for mechanical ventilation, any neonatal intensive care unit entrance and any respiratory insufficiency symptoms.

Secondary outcome measures

Morbidity of the mother if administering regional anesthesia compared to general anesthesia

Overall study start date
01/07/2015

Completion date
06/12/2015

Eligibility

Key inclusion criteria
1. Female
2. Age between 18-45
3. BMI<40
4. Patients diagnosed as being in fetal distress.
5. Patients without neurological diseases
6. Patients consenting to join the study

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
45 Years

Sex
Female

Target number of participants
60 patients will be included.

Key exclusion criteria
1. Age less than 18 and older than 45
2. BMI>40
3. Patients that refuse to join study

Date of first enrolment
01/07/2015

Date of final enrolment
06/12/2015

Locations

Countries of recruitment

Türkiye

Study participating centre
Suleymaniye Birth And Women's Health Education And Research Hospital
Telsiz Mah. Balıklı Kazlıcesme Yolu No:1 Zeytinburnu
Istanbul
Türkiye
34116

Sponsor information

Organisation
Suleymaniye Birth And Women's Health Education And Research Hospital

Sponsor details
Telsiz Mah. Balıklı Kazlıcesme Yolu No:1 Zeytinburnu
Istanbul
Türkiye
34116

Sponsor type
Government

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Suleymaniye Birth And Women's Health Education And Research Hospital (Turkey)

Results and Publications

Publication and dissemination plan

Intention to publish date
01/02/2016

Individual participant data (IPD) sharing plan

Not provided at time of registration

IPD sharing plan summary

Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	16/11/2018		Yes	No
Protocol (other)			10/03/2023	No	No