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Complications in pregnancies with big babies

Submission date	Recruitment status	[_] Prospectively registered
27/02/2019	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
01/03/2019	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
29/03/2021	Pregnancy and Childbirth	

Plain English summary of protocol

Background and study aims
Pregnancies with big babies are associated with maternal complications, such as emergency caesarean section, post-partum hemorrhage (heavy bleeding after delivery) and perineal trauma and neonatal complications, including shoulder dystocia, brachial plexus injury (OBPI), fracture of humerus or clavicle and birth asphyxia. Despite the association of big babies with pregnancy complications as well as its relatively common occurrence in clinical practice, there is lack of a clear consensus regarding management of pregnancies with big babies with no guidance from professional bodies on either the identification, diagnosis nor management of when there is a diagnosis of a big baby during the pregnancy. The aims of our study are firstly, to compare the prevalence of pregnancy complications in pregnancies with big babies compared to those that are not; secondly, to determine whether complications in pregnancies with big babies can be predicted effectively from maternal and pregnancy characteristics and thirdly, in pregnancies that are deemed to be high risk, we aim to assess whether delivery at an earlier gestation is associated with a reduction in the incidence of adverse outcomes.

Who can participate?
Health records from singleton pregnancies with healthy babies from the last 8-9 years will be analysed.

What does the study involve?
The study is retrospectively analysing health records.

What are the possible benefits and risks of participating?
Not applicable

Where is the study run from?
Medway NHS Foundation Trust, Fetal Medicine Unit, Gillingham, Kent, ME7 5NY

When is the study starting and how long is it expected to run for?
January 2009 to March 2019

Who is funding the study?
Health Education England, Kent Surrey and Sussex

Who is the main contact?
Professor RanjitAkolekar, ranjit.akolekar@canterbury.ac.uk

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
262820

Study information

Scientific Title
Maternal and neonatal outcomes in pregnancies with macrosomia

Study objectives
The aim of this study is firstly, to compare the prevalence of pregnancy complications in pregnancies with big babies compared to those that are not; secondly, to determine whether complications in pregnancies with big babies can be predicted effectively from maternal and

pregnancy characteristics and thirdly, in pregnancies that are deemed to be high risk, we aim to assess whether delivery at an earlier gestation is associated with a reduction in the incidence of adverse outcomes.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at the time of registration

Awaiting approval from London - City & East Research Ethics Committee (Henry VIII Committee Room, St Bartholomew's Hospital, North Wing, EC1A 7BE; 0207 1048033; nrescommittee.london-cityandeast@nhs.net), ref: 19/LO/0502 (IRAS ID 262280).

Study design
Retrospective cohort study

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
Hospital

Study type(s)
Screening

Participant information sheet
None needed (retrospective study)

Health condition(s) or problem(s) studied
Pregnancy complications in big babies

Interventions
This is a retrospective cohort study undertaken at the Fetal Medicine Unit at a large maternity unit in United Kingdom. In our unit, all women who book for their pregnancy care are offered routine scans at 11-13 weeks, 20-22 weeks and 35-37 weeks for assessment of fetal anatomy, fetal growth and well-being. At the 11-13 weeks' and 20-22 weeks' gestation, we record maternal demographic characteristics and obtain detailed medical and obstetric history to allow for risk assessment of pregnancies at risk of placental dysfunction. Women who are diagnosed with large for gestational age at 35-37 weeks are offered an additional scan at 39-40 weeks' gestation to assess fetal growth and well-being.

There is a specific dedicated team of fellows and sonographers who are trained in advanced obstetric ultrasound scanning who carry out an ultrasound scan to assess fetal growth and well-being by examination of fetal biometry, amniotic fluid and feto-placental Dopplers. Women who have a diagnosis of large for gestational age pregnancies are referred to the Fetal Medicine Consultant for a discussion about the risks and benefits of timing and mode of delivery.

The inclusion criteria for this study will include singleton pregnancies during the study period and those that delivered a phenotypically normal neonate after 24 weeks' gestation. We excluded multiple pregnancies, miscarriages, termination of pregnancies, those with major fetal defects and pregnancies lost to follow-up.

Intervention Type
Other

Primary outcome measure
The primary outcome measures were divided into maternal and neonatal complications.
Maternal complications:
1. Rates of emergency cesarean section, post-partum haemorrhage and obstetric anal sphincter injury (OASIS).
Neonatal complications:
1. Rates of shoulder dystocia, obstetric brachial plexus injury, birth fractures and hypoxic-ischaemic encephalopathy.

Secondary outcome measures
Maternal secondary outcome measures:
Rates of:
1. Prolonged 1st and 2nd stage of labor
2. Instrumental vaginal delivery
3. Failed instrumental delivery requiring cesarean section
4. Emergency cesarean section for failure to progress.

Overall study start date
01/06/2018

Completion date
01/05/2019

Eligibility

Key inclusion criteria
1. Singleton pregnancies which booked and delivered at our hospital during the study period
2. Delivered phenotypically normal neonates at ≥ 24 weeks' gestation

Participant type(s)
Patient

Age group
Adult

Sex
Female

Target number of participants
Approximately 40,000 pregnancies, including about 4,000 with birthweight > 4,000g and about 500-600 with birthweight > 4,500 g.

Total final enrolment
35548

Key exclusion criteria
1. Multiple pregnancies
2. Miscarriages
3. Terminations of pregnancy
4. Major fetal defects
5. Lost to follow-up

Date of first enrolment
01/01/2009

Date of final enrolment
01/03/2019

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Medway NHS Foundation Trust
Fetal Medicine Unit,
Level 2, Green Zone,
Windmill Road
Gillingham
United Kingdom
ME7 5NY

Sponsor information

Organisation
Medway NHS Foundation Trust

Sponsor details
Research and Innovation Department
Windmill Road,
Gillingham
England
United Kingdom

ME7 5NY
01634830000 ext 3129
hayley.beresford1@nhs.net

Sponsor type
Hospital/treatment centre

Website
NA

ROR
https://ror.org/01apxt611

Funder(s)

Funder type
Government

Funder Name
Health Education England, Kent Surrey and Sussex

Results and Publications

Publication and dissemination plan
We aim to publish the data in peer-reviewed scientific journals.

Intention to publish date
01/04/2019

Individual participant data (IPD) sharing plan
The current data sharing plans for this study are unknown and will be available at a later date

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		01/09/2019	29/03/2021	Yes	No
HRA research summary			26/07/2023	No	No