

# Complications in pregnancies with big babies

<b>Submission date</b> 27/02/2019	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 01/03/2019	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 29/03/2021	<b>Condition category</b> Pregnancy and Childbirth	<input type="checkbox"/> Individual participant data

## 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

### Contact name

Prof Ranjit Akolekar

### ORCID ID

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### Contact details

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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  $\geq 24$  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  $> 4,000$ g 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?
<a href="#">Results article</a>		01/09/2019	29/03/2021	Yes	No
<a href="#">HRA research summary</a>			26/07/2023	No	No