

Improving detection of small infants during pregnancy

| | | |
|--|---|--|
| Submission date 27/06/2016 | Recruitment status No longer recruiting | <input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol |
| Registration date 02/11/2016 | Overall study status Completed | <input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results |
| Last Edited 09/01/2024 | Condition category Pregnancy and Childbirth | <input type="checkbox"/> Individual participant data |

Plain English summary of protocol

Background and study aims

Stillbirth is when a baby dies in the womb and has to be delivered. It is a tragedy with lifelong consequences for parents and their family and friends. In the UK the number of babies stillborn has not fallen in the past 20 years, and currently affects 1 in every 200 pregnancies. This means that stillbirth in the UK is amongst the highest in Europe. Doctors, midwives and politicians want to change this, and recently reducing stillbirths has been identified as a priority. Most babies that die before birth are normal, but many weigh less than expected. One of the most common reasons for these baby deaths is poor growth in the womb. Often this has gone unnoticed by the doctors and midwives. A baby's growth in the womb relies on the placenta (afterbirth) working well and providing all the nutrients the baby needs. There are many reasons why the placenta does not work well, and in most cases, with the exception of stopping cigarette smoking, there is little the mother can do to improve this. But most small babies are healthy and growing normally. They are small because of genes inherited from their parents. Factors like parents' body size and ethnic background are likely to help doctors and midwives work out which babies are small but growing normally and which are small because their placenta is not working well. These babies could be at risk of being stillborn. Previously, a large study has suggested that a package known as Growth Assessment Protocol (GAP), which takes these factors into account, has reduced the stillbirth rates in three regions of the UK. However, there are many other possible reasons other than the GAP that could have led to the reduction in stillbirths in this study. The aim of this study is to look at the impact of the GAP, and whether it really does reduce stillbirths, so that doctors, midwives and policy makers will know whether they should put resources in place to use GAP in all NHS hospitals.

Who can participate?

Pregnant women delivering their baby at a participating hospital.

What does the study involve?

Participating maternity units are randomly allocated to one of two groups. Those in the first group will provide care according to the GAP programme (immediate implementation). For participating women, this involves a standardized way of having their risk of having a baby that is too small for its age assessed at 12 weeks and screening for small infants after 24 weeks using customized centiles (measurements) according to GAP principles. Those in the second group

receive usual care, which could involve having their risk of having a baby that is too small for its age assessed at 12 weeks and screening methods for small babies after 24 weeks based as per routine care. Participants in both groups are followed up until delivery by the clinical team in their hospital to find out if they had a small baby.

What are the possible benefits and risks of participating?

There are no direct benefits or risks involved with participating in this study.

Where is the study run from?

Maternity units across 13 NHS Trusts in England (UK)

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

January 2015 to October 2018

Who is funding the study?

Tommys (UK)

Who is the main contact?

Dr Matias Costa Vieira

matias.vieira@kcl.ac.uk

Contact information

Type(s)

Scientific

Contact name

Dr Matias Costa Vieira

ORCID ID

<http://orcid.org/0000-0002-8076-4275>

Contact details

Division of Women's Health

King's College London

10th Floor North Wing

St Thomas' Hospital

Westminster Bridge Road

London

United Kingdom

SE1 7EH

+44 7188 7188 ext. 52545

matias.vieira@kcl.ac.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

20296

Study information

Scientific Title

The DESiGN Trial: Detection of small for gestational age fetus (SGA) – a cluster randomised controlled trial to evaluate the effect of the Growth Assessment Protocol (GAP) programme

Acronym

DESiGN

Study objectives

The GAP programme improves the detection of small for gestational age fetuses when compared to current clinical practice.

Ethics approval required

Old ethics approval format

Ethics approval(s)

London - Bloomsbury Research Ethics Committee, 29/02/2016, ref: 15/LO/1632

Study design

Randomised; Interventional; Design type: Screening, Diagnosis, Complex Intervention

Primary study design

Interventional

Secondary study design

Cluster randomised trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied

Specialty: Reproductive health and childbirth, Primary sub-specialty: Reproductive and sexual medicine

Interventions

Hospitals will be randomized to one of two groups. The method of allocation is the random permutation of clusters within each of two equally sized strata; clusters are divided in the two

strata according to their size (deliveries per year in 2013-2014) and then randomized to either early or delayed implementation.

Early implementation arm: The GAP programme will be immediately implemented with training and the use of protocols consistent with the principles of GAP. Women in this study arm will be risk assessed for SGA and managed as per GAP protocol. Low risk women will be seen routinely in antenatal clinic. At these visits standardised FH measurements will be performed from 28 weeks. In high risk women serial ultrasounds after 24 weeks will be recommended. Customised FH and ultrasound charts will be generated at the first trimester ultrasound visit. FH measurements will be plotted on the customised FH chart. In low risk women any deviation in growth on these charts will result in recommendation for ultrasound measurement. Estimated fetal weight (EFW) from ultrasound measurements will be plotted on customised EFW charts for both low or high risk women whenever an ultrasound is done.

Delayed implementation arm: Women will have a risk assessment according to routine practice (if available) and screening for SGA according to local protocol (if available) and use of population charts as reference for diagnosis of SGA in antenatal ultrasounds. GAP will be introduced after the data collection for outcomes.

Majority of participating women will not be required to return for additional research visits but some women in the study will be approached by the research team and invited to take part in interviews to explore the experience of receiving care in line with GAP programme. Source of data will vary according to the outcome assessed. Most of the data will be acquired from routine hospital data. This will include mainly electronic records but also review of some clinical notes. Data will be obtained from hospital maternity electronic systems which record antenatal, ultrasound, intrapartum, postnatal and neonatal information. Data obtained manually from clinical notes will be entered into a trial database. For the implementation component of the study primary data collection from interviews and focus groups will be performed.

Intervention Type

Other

Primary outcome measure

Detection rate of SGA infants measured by ultrasound after 24 weeks* is assessed using data from the maternity and ultrasound system between months 13 to 18 of study.

* The antenatal charts used for ultrasound detection (numerator) will depend on the allocation arm of the trial. The denominator for the estimation of detection in each arm of the trial will be the same population of SGA infants (birthweight <10th centile) by both customised and population

Secondary outcome measures

1. Detection rate (sensitivity), specificity, false positive and false negative of SGA by customised centiles measured by ultrasound after 24 weeks
2. Detection rate (sensitivity), specificity, false positive and false negative of SGA by population centiles measured by ultrasound after 24 weeks

Clinical outcomes:

Neonatal:

1. Gestational age measured in weeks at birth
2. Birthweight measured in grams at birth

3. Head circumference measured in centimeters at birth
4. Apgar score <7 measured using Apgar scale at birth
5. Metabolic acidosis defined as an arterial cord pH<7.1 at birth
6. Rate or need of respiratory support in delivery room at birth
7. Rate of neonatal intensive care after birth
8. Length of stay in neonatal intensive care unit (NICU) measured in days
9. Level of care needed in NICU
10. Rate of major neonatal morbidity defined as one or more of the following: intraventricular haemorrhage, supplementary oxygen requirements > 28 days, necrotizing enterocolitis, sepsis, retinopathy of prematurity
11. Length of stay in transitional care measured in days
12. Rate of neonatal morbidity defined as one or more of the following: hypothermia, hypoglycaemia, nasogastric tube feeding
13. Rate of stillbirth (antepartum and intrapartum)
14. Rate of neonatal death (early and late)
15. Rate of neonatal death before discharge (after 28 days of birth)

Maternal:

1. Rate of induction of labour measured at birth
2. Rate of caesarean section measured at birth
3. Rates of postpartum haemorrhage (>1000ml) measured at birth
4. Rate of severe perineal trauma (3rd / 4th degree tear) measured at birth
5. Length of stay in hospital measured in days
6. Method of breast feeding measured at discharge

Health economics outcomes:

1. Number of ultrasound scans after 24 weeks measured at delivery (as average of ultrasound per women)
2. Number of antenatal clinic / antenatal day unit measured at delivery (as average of ultrasound per women)

Process evaluation of implementation outcomes:

1. Proportion of staff trained measured at the end of training period (expected to be at month 6 of study)
2. Proportion of staff assessed for GAP training at the end of training period (expected to be at month 6 of study)
3. Proportion of women assessed with GAP programme measured throughout the study by review of notes of a sample of participants
4. Adherence to SGA risk stratification and management protocols and missed case analysis measured throughout the study and assessed by hospital level data (data available from risk assessment)

Outcomes for other methods of assessments of antenatal detection of SGA:

1. Detection rate of SGA (birthweight<5th centile) measured by ultrasound after 24 weeks
2. Detection of SGA infants measured as clinical detection before birth (review of notes)

Overall study start date

01/01/2015

Completion date

30/11/2019

Eligibility

Key inclusion criteria

Hospitals:

1. Willing to implement GAP
2. Willing to participate in the trial

Patients:

1. Pregnant women
2. Delivering at one of the participating hospitals during the study period

Participant type(s)

Patient

Age group

Adult

Sex

Both

Target number of participants

Planned Sample Size: 108; UK Sample Size: 108

Key exclusion criteria

Hospitals that have fully implemented or will not be introducing GAP.

Date of first enrolment

01/12/2016

Date of final enrolment

30/04/2018

Locations

Countries of recruitment

England

United Kingdom

Study participating centre

Guy's and St Thomas' NHS Foundation Trust

Great Maze Pond

London

United Kingdom

SE1 9RT

Study participating centre
Homerton University Hospital NHS Foundation Trust
Homerton Row
London
United Kingdom
E9 6SR

Study participating centre
University College London Hospitals NHS Foundation Trust
250 Euston Road
London
United Kingdom
NW1 2PG

Study participating centre
St George's Healthcare NHS Trust
Blackshaw Road
London
United Kingdom
SW17 0QT

Study participating centre
Kingston Hospital NHS Trust
Galsworthy Road
Kingston upon Thames
United Kingdom
KT2 7QB

Study participating centre
Croydon Health Services NHS Trust
London Road
Thornton Heath
United Kingdom
CR7 7YE

Study participating centre
Imperial College Healthcare NHS Trust
Pread Street
London
United Kingdom
W2 1NY

Study participating centre

The Hillingdon Hospitals NHS Foundation Trust

Pield Heath Road

Uxbridge

United Kingdom

UB8 3NN

Study participating centre

North West London Hospitals NHS Trust

Watford Road

Harrow

United Kingdom

HA1 3UJ

Study participating centre

West Middlesex University Hospital NHS Trust

Twickenham Road

Isleworth

United Kingdom

TW7 6AF

Study participating centre

Royal Surrey County Hospital NHS Foundation Trust

Egerton Road

Guildford

United Kingdom

GU2 7XX

Study participating centre

North Middlesex University Hospital NHS Trust

Sterling Way

London

United Kingdom

N18 1QX

Study participating centre

Chesterfield Royal Hospital NHS Foundation Trust

Chesterfield Road

Chesterfield
United Kingdom
S44 5BL

Sponsor information

Organisation

Comprehensive Clinical Trials Unit at UCL

Sponsor details

University College London
Gower Street
London
England
United Kingdom
WC1E 6BT

Sponsor type

Hospital/treatment centre

ROR

<https://ror.org/02jx3x895>

Funder(s)

Funder type

Charity

Funder Name

Tommy's Baby Charity

Alternative Name(s)

Funding Body Type

Private sector organisation

Funding Body Subtype

Other non-profit organizations

Location

United Kingdom

Funder Name

Stillborn and Neonatal Death Charity

Alternative Name(s)

SANDS

Funding Body Type

Private sector organisation

Funding Body Subtype

Associations and societies (private and public)

Location

United Kingdom

Funder Name

Guy's and St Thomas' Charity

Alternative Name(s)

Guy's and St Thomas' Charity, Guy's and St Thomas' Foundation, GSTTFoundation

Funding Body Type

Private sector organisation

Funding Body Subtype

Trusts, charities, foundations (both public and private)

Location

United Kingdom

Results and Publications

Publication and dissemination plan

The results of the trial will be disseminated regardless of the direction of effect to the scientific and non-scientific community. The main results will be presented in a scientific conference and published in a peer-reviewed journal. The plan is to submit the main results for publication within 2 months of the end of the trial.

Intention to publish date

28/02/2020

Individual participant data (IPD) sharing plan

The anonymised data will be stored centrally by the sponsor (Clinical Trials Unit at University College London).

IPD sharing plan summary

Stored in repository

Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---------------------------|--------------|------------|----------------|-----------------|
| Protocol article | protocol | 04/03/2019 | 07/03/2019 | Yes | No |
| Interim results article | sub-study results | 08/03/2021 | 10/03/2021 | Yes | No |
| Results article | Health economics outcomes | 05/09/2022 | 06/09/2022 | Yes | No |
| HRA research summary | | | 28/06/2023 | No | No |
| Results article | | 07/07/2022 | 09/01/2024 | Yes | No |