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Feasibility and design of a trial to determine the optimal mode of delivery in women presenting in preterm labour or with planned preterm delivery: CASSAVA

Submission date
15/10/2018

Recruitment status
No longer recruiting

Registration date
26/10/2018

Overall study status
Completed

Last Edited
10/11/2021

Condition category
Pregnancy and Childbirth

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

Plain English summary of protocol

Background and study aims
This study is a commissioned call from the Health Technology Assessment (HTA) because the National Institute for Clinical Excellence (NICE) guideline development group on preterm labour and birth were unable to find evidence about the optimal method of delivery for preterm babies. Addressing this clinical uncertainty could improve the rates of stillbirth, neonatal and long-term mortality and morbidity, which are higher in the 50,000 preterm babies born in the UK each year compared with term babies. It is possible that planned delivery by caesarean section (CS) could reduce either death or disability in preterm babies.
However, birth by caesarean section is also associated with higher costs and greater complications for the mother, and there is conflicting evidence of the benefit for preterm babies. Due to the lack of evidence and uncertainty in the national guidance, clinicians and pregnant women are unclear about the best mode of delivery for preterm pregnant women and babies, nor whether they would wish to participate in any future randomised trial. Randomised trials have been performed to address optimal mode of delivery for women with breech presentation and women with twin pregnancy and these trials have reduced uncertainty. However, there are very few randomised trials to compare planned caesarean section with a planned vaginal delivery for women at term, and none for preterm gestations.
The aim of this study is to identify the clinical uncertainties among staff and the public, any additional information possible (e.g. from new publications), and to find out whether women and staff (and if so, under what clinical circumstances) would be willing to participate in a randomised trial.

Who can participate?
Members of the public (men and women aged over 16) and clinical staff working in hospitals with a Neonatal Intensive Care Unit

What does the study involve?
Participants will be asked to answer a short survey and take part in interactive workshops, along with interviews and focus groups.

What are the possible benefits and risks of participating?
There are no known benefits or risks to participants taking part in this study.

Where is the study run from?
This study is run from the University of Edinburgh and the study centres will be NHS Lothian, University College Hospital Foundation Trust and North Bristol NHS Trust (UK)

When is the study starting and how long is it expected to run for?
November 2018 to November 2020

Who is funding the study?
NIHR Health Technology Assessment Programme (UK)

Who is the main contact?
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Study website
https://www.ed.ac.uk/centre-reproductive-health/cassava

Contact information

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Public

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
39568

Study information

Scientific Title
Feasibility and design of a trial to determine the optimal mode of delivery in women presenting in preterm labour or with planned preterm delivery: CASSAVA

Acronym
CASSAVA

Study objectives
This research aims to find out the groups of women and babies in preterm labour or with planned preterm delivery in whom is there clinical uncertainty about the optimal planned mode of birth, and whether women and clinical staff would be willing to participate in a future randomised trial.

Ethics approval required
Old ethics approval format

Ethics approval(s)
London - City & East Research Ethics Committee , 17/09/2018, ref: 18/LO/1616

Study design
Observational; Design type: Qualitative

Primary study design
Observational

Secondary study design

Survey results, working group report and consensus statement, protocol for randomised trial, and reports from qualitative studies

Study setting(s)
Hospital

Study type(s)
Treatment

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

Health condition(s) or problem(s) studied
Preterm delivery

Interventions
This research will use a series of surveys (public and stuff), a Delphi consensus workshop, interviews and focus groups with clinical staff and the public to find out the groups of women and babies in preterm labour or with planned preterm delivery in whom is there clinical uncertainty about the optimal planned mode of birth, groups and whether women and clinical staff would be willing to participate in a future randomised trial.
Phase 1 of this study will involve 200 members of the public and 200 clinicians completing a short 10 minute online survey.
Phase 2 is a Delphi consensus workshop of 3 rounds:
1. A web-based questionnaire
2. Rescoring preferences to achieve consensus
3. Final consensus meeting
This will include around 20-40 participants.
Phase 3 involves interviews with clinical staff, lasting for up to 1 hour, and 6-8 focus groups of 5-8 members of the public each.

Intervention Type
Other

Primary outcome measure
Phase 1:
Current practice and opinions, assessed using surveys conducted during months 0-4 informing the Delphi consensus

Phase 2:
Clinical uncertainties, assessed using a Delhi consensus conducted during months 5-9 informing the development of a randomised control trial protocol to be used in phase 3

Phase 3:
1. Willingness to recruit to a randomised controlled trial, assessed through interviews with clinical staff during months 10-22
2. Willingness to participate in a randomised controlled trial, assessed through focus groups during months 10-22

Secondary outcome measures

N/A

Overall study start date
01/03/2018

Completion date
31/10/2020

Eligibility

Key inclusion criteria
Phase 1
Clinicians who work in hospitals with neonatal intensive care units (any of the following):
1. Consultant obestricians
2. Neonatologists
3. Midwives

Members of the public:
1. Interested in supporting and commenting on research projects

Phase 2
Clinicians with 5 years or more experience of providing clinical care to women at risk of preterm labour or preterm infants born (any of the following):
1. Obstetricians
2. Anaesthetists
3. Midwives
4. Nurses
5. Neonatologists
6. Midwives

Women and their partners who fulfill the following criteria:
1. Aged 16 years or older
2. Willing to consent
3. Previous experience of any of the following:
3.1. Previous preterm labour or delivery
3.2. At risk of future preterm labour or delivery

Phase 3
Clinicians with 5 years or more experience of providing clinical care to women at risk of preterm labour or preterm infants born (any of the following) who have taken part in phases 1 and 2:
1. Obstetricians
2. Anaesthetists
3. Midwives
4. Nurses
5. Neonatologists
6. Midwives

Women who fulfill the following criteria:
1. Aged 16 years or older
2. Willing to consent
3. Previous experience of any of the following:

3.1. Previous preterm labour or delivery
3.2. At risk of future preterm labour or delivery

Participant type(s)
Mixed

Age group
Adult

Sex
Both

Target number of participants
Planned Sample Size: 525; UK Sample Size: 525

Key exclusion criteria
Phase 2 and 3
Women and their partners who have experienced adverse events as a result of the issues above (e.g. neonatal death, stillbirth) will not be actively excluded from the consensus workshops or focus groups, but we will be mindful of the need to manage this sensitively. The members of the research team have significant experience of conducting mixed-methods research with parents who have experienced adverse events, including perinatal death.

Date of first enrolment
01/11/2018

Date of final enrolment
31/08/2020

Locations

Countries of recruitment
England

Scotland

United Kingdom

Study participating centre
NHS Lothian Royal Infirmary of Edinburgh
Site 47
Little France Crescent
Edinburgh
United Kingdom
EH16 4TJ

Study participating centre

University College Hospital Foundation Trust
Elizabeth Garrett Anderson Wing
25 Grafton Way
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Sponsor information

Organisation
The University of Edinburgh and/or Lothian Health Board

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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/01nrxwf90

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research (NIHR); Grant Codes: 2018/0248

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
The results of this study will form a report to HTA to allow them to decide whether to commission a future trial. However, we anticipate that the findings of this trial will also be suitable for journal publications. We will also disseminate the results through our charity partners (Tommy's and BLISS).

Intention to publish date
31/10/2022

Individual participant data (IPD) sharing plan
Anonymized data will be shared (if requested) with other researchers within the European Union as per the funders data sharing policy.

The protocol has been uploaded as an additional file (not peer reviewed) (added 10/12/2019)

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file	version v2	15/10/2018	10/12/2019	No	No
Results article		01/11/2021	10/11/2021	Yes	No
HRA research summary			26/07/2023	No	No