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Prevention of cerebral palsy in pre-term labour

Submission date
27/01/2020

Recruitment status
No longer recruiting

Registration date
04/03/2020

Overall study status
Completed

Last Edited
17/05/2022

Condition category
Pregnancy and Childbirth

[ ] Prospectively registered
[X] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Preterm birth is the leading cause of brain injury and Cerebral Palsy (CP) with lifelong impact on children and families. Magnesium sulphate (MgSO4) given to eligible mothers during preterm birth is an effective treatment for protecting the baby's brain. High quality evidence suggests that CP can be reduced in a third of cases. More than half of UK premature babies are not receiving the benefit of this highly cost-effective treatment. The dose costs approximately £1.

A quality improvement (QI) package, PReCePT1, was co-designed with patients and staff and implemented across five maternity units in West-England, increasing average uptake from 21%, over the two years preceding the study, to 85%. PReCePT1 contributed to the NICE Guideline (published 2016) that recommends Magnesium Sulphate should be given to all women in preterm labour (below 30 weeks gestation) as brain protection for the baby.

Following the success of PReCePT1, NHS England are funding the national PReCePT Programme (NPP), to roll out the PReCePT QI toolkit in maternity units in England, resourced by the regional Academic Health Science Networks.

The PReCePT Study is a research trial embedded within the NPP to evaluate the effectiveness of an enhanced support implementation model versus the standard support implementation model, as deployed by the NPP, as a prospective comparison.

Who can participate?
Maternity units in England: participating in national PReCePT Programme (NPP); with minimum of 10 preterm (<30 weeks GA) births in 2016; and with 70% or less magnesium sulphate uptake in 2016

What does the study involve?
All units will receive training, PReCePT resources and time to train their colleagues. The 16 units receiving enhanced support will also have structured input from a QI-Coach and funded time to micro-coach their local teams. The study intervention period will be 9 months, with a 9 month follow up period using routinely collected data.

What are the possible benefits and risks of participating?
Units randomised to the enhanced support model will benefit from an intensified level of

support to assist them with embedding the QI toolkit in their unit. There will be no direct benefits to units in the control arm, however all units in the study will contribute important evidence about how best to work with maternity units to ensure that high quality evidence from NICE national guidelines can be implemented in practice.
There are no clear disadvantages or risks to taking part.

Where is the study run from?
St Michael's Hospital (UK)

When is the study starting and how long is it expected to run for?
August 2018 to May 2021 (updated 10/11/2020, previously: November 2020)

Who is funding the study?
1. Health Foundation (Scaling Up Improvement Programme) (UK)
2. NIHR ARC West (UK)
3. West of England AHSN (UK)

Who is the main contact?
Dr Karen Luyt
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Study website
https://arc-w.nihr.ac.uk/research/projects/ preventing-cerebral-palsy-in-pre-term-babies-the-precept-study/

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

242419

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
CPMS 39733, IRAS 242419

Study information

Scientific Title
PReCePT Study – A cluster randomised trial evaluating the impact of an enhanced support implementation of the PReCePT quality improvement toolkit to increase the uptake of magnesium sulphate in pre-term deliveries for the prevention of neurodisabilities

Acronym
PReCePT2

Study objectives
The PReCePT QI toolkit implemented with an enhanced support model will be more effective in improving MgSO4 uptake than a standard support model, yet more costly due to clinical backfill and external coaching.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approval not required by HRA. As a type A study, the project does not require review by an ethical committee. The intervention is aimed at staff by way of QI training. There is no patient recruitment.

Study design
Interventional randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Other

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
Neonatal health

Interventions
The PReCePT Study is a multicentre randomised controlled trial (non-blinded) that will be embedded in the national PReCePT Programme (NPP). Maternity units in England that are part of the NPP are potentially eligible for participation in the PReCePT Study.

Two groups are being evaluated and compared in the trial and are recruited among eligible maternity units in England. Depending on trial allocation, units will receive:
Group 1: Implementation of the PReCePT Quality Improvement (QI) toolkit according to the standard support model, as defined and deployed by the local AHSN within the NPP. This includes provision of PReCePT QI materials and some support funding for the regional-level training/coaching and clinical backfill (local midwife).
Group 2: Implementation of the PReCePT Quality Improvement (QI) toolkit according to the enhanced support model. After participating in the initial implementation stage of the NPP, the level of support will be intensified for units receiving enhanced support, providing more comprehensive QI coaching, participating in three learning events, funded time for local clinical champions to coach the team and lead the QI implementation (local midwife and local neonatologist) and a small fund for study collateral;

Forty-eight maternity units in England will be randomised to either receive the enhanced support model (16 units) or be observed while implementing the standard support model (32 units).

PReCePT QI toolkit is a multifaceted approach to increase awareness and knowledge among maternity unit staff about magnesium sulphate as brain protection in preterm deliveries. It provides practical tools and training to support staff in acute clinical settings to consider magnesium sulphate in eligible pregnancies.

Implementation of the PReCePT QI toolkit will be led by local midwives and an obstetrician champion in their own maternity unit. Units in the enhanced support group will also have a local neonatologist (0.5 PA / 2 hours a week) to provide clinical leadership and oversee implementation.

The PReCePT Study evaluation team will identify participants (maternity units) according to inclusion/exclusion criteria. Based on National Neonatal Audit programme published data for 2016, we anticipate that 96 units will be eligible for inclusion in the study.

The study team will contact eligible Trusts/units according to HRA guidance for collaborative working where no formal confirmation of capacity and capability is required. A local information pack will be provided, which will include a unit information sheet, consent form and invitation letter describing the project, with contact details for the study team in case of further questions. Units that 'opt in' to participate in the trial will provide written informed consent at unit level before commencing the study.

Staff in participating units who are eligible and selected for interviews will be provided with a participant information sheet describing the interview and the procedures for audio recording, transcription and the storage of data, with contact details for the study team in case of further questions. Staff agreeing to participate in telephone or internet mediated interviews, or face-to-face if feasible, will be asked to provide verbal (proportionate) consent for the audio-recording of interviews.

Following the intervention period of nine months, there will be a follow up period of nine months, after which routinely collected data will be obtained from the registries and analysed to assess the uptake and sustainability of the QI intervention.

The NPP is implementing the PReCePT QI toolkit across all NHS England units in two tranches: the first tranche started in May 2018, the second will start in September 2018. To maintain optimal comparability of the two trial groups, the randomisation procedure and implementation according to the enhanced support model of the PReCePT Study will be aligned with this timeframe. As such, the first 8 units will be randomly selected from units participating in the first tranche, 3 months later the second group will be randomised from the second tranche.

Implementation for enhanced support in units from the first tranche will start in October 2018; for those from the second tranche, implementation will start in January 2019. The follow-up periods to evaluate the outcomes will reflect the same time-delay associated with the tranches.

The PReCePT Study will prospectively evaluate the effectiveness of the enhanced support model by comparing the MgSO4 uptake of the units randomised to the enhanced support model compared to those that were observed under the standard support model. The study aims to establish the added value (impact) and costs of the enhanced support model compared to the standard support model.

Intervention Type
Other

Primary outcome measure
The proportion of eligible mothers given MgSO4 in the 9 months after the implementation of the QI intervention, adjusting for the proportion in the 12 months before implementation

Secondary outcome measures
1. Proportion of preterm babies receiving MgSO4 will be analysed, testing for step-change or change in trend in the 12-month period before, during (9 months) and 9-month period after the implementation of the PReCePT QI package.
2. Completeness of registration of MgSO4 use and reasons not given MgSO4 (proportion of missing entries) will be measured at baseline (the 12-month period before implementation) and 9 months after the implementation of the QI intervention
3. Health economic evaluation – the estimation of the policy cost-effectiveness involving the identification, measurement and valuation of resources used for the different phases of the enhanced QI (i.e., developmental, organising, executing and sustainability costs) versus the standard support during the 9 months of the intensive coaching and three months of sustainability
4. Process evaluation using qualitative interviews carried out prior to the end of the period of implementation with follow-up interviews carried out at the end of the evaluation period to inform sustainability assessment. Process evaluation – will include:
4.1. Proportion of staff receiving training
4.2. Type of staff receiving training (job role)
4.3. Number and duration of training sessions for each unit
4.4. Time required to deliver / receive training
4.5. Staff confidence post training
4.6. Number of staff meetings and staff present where feedback reports are discussed
4.7. Previous experience with QI projects in each unit

4.8. Other ongoing (QI/scientific) projects in each unit
4.9. Organisational/restructuring activities in unit/department
4.10. Understaffing, changes in management/senior staff, etc.
4.11. Adherence to activities and actions of the PReCePT QI toolkit
4.12. Staff involvement and engagement
4.13. Perceived support by unit/ Trust leadership
4.14. Contextual factors that may have influenced the implementation and observed outcomes, e.g. organisational changes, staff shortages
4.15. Professional, organisational or cultural issues that affected implementation

Overall study start date
01/12/2017

Completion date
31/05/2021

Eligibility

Key inclusion criteria
1. Units in England participating in national PReCePT Programme (NPP)
2. Units with minimum of 10 preterm (<30 weeks GA) births in 2016
3. Units with 70% or less magnesium sulphate uptake in 2016

Participant type(s)
Patient

Age group
Other

Sex
Both

Target number of participants
Planned Sample Size: 48; UK Sample Size: 48

Total final enrolment
99

Key exclusion criteria
Units previously participating in PReCePT1

Date of first enrolment
23/08/2018

Date of final enrolment
31/10/2020

Locations

Countries of recruitment

England

United Kingdom

Study participating centre
St Michael's Hospital
University Hospitals Bristol NHS Foundation Trust
Southwell Street
Bristol
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BS2 8EG

Sponsor information

Organisation
University Hospitals Bristol NHS Foundation Trust

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Sponsor type
Hospital/treatment centre

Website
http://www.uhbristol.nhs.uk/

ROR
https://ror.org/04nm1cv11

Funder(s)

Funder type
Charity

Funder Name
Health Foundation; Grant Codes: 557668

Funder Name
NIHR ARC West

Funder Name
West of England AHSN

Results and Publications

Publication and dissemination plan
Publish and share the results of the study in relevant professional network publications, including peer-reviewed journals.

2020 preprint protocol in https://doi.org/10.1101/2020.09.10.20190322 (added 10/11/2020)

Intention to publish date
31/12/2022

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are not expected to be made available due to data protection.

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	10/05/2021	30/09/2021	Yes	No