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Optimising neonatal service provision for preterm babies born between 27 and 31 weeks of gestation in England

Submission date
27/02/2017

Recruitment status
No longer recruiting

Registration date
06/03/2017

Overall study status
Completed

Last Edited
23/04/2025

Condition category
Neonatal Diseases

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

Plain English summary of protocol

Background and study aims
Things that happen early in a baby's life are very important for his/her later health and development. Premature babies, born several weeks before their due date, are often very ill in the first weeks and months of life, compared with those born at full term. Because babies' brains and bodies are still developing at this time, early birth puts them at increased risk of later problems with health and development. It is important that we do everything we can to try to improve the overall health of these children. Not only will this help children and families, but it will also help improve understanding of the correct amount and type of care they will need from the NHS in the future. At present, England has three types of neonatal units: Neonatal Intensive care units (NICUs) that can care for the most sick and most premature babies, Local Neonatal Units (LNUs) that generally care for slightly less sick babies, and Special Care baby units (SCBU) that care for larger premature babies who are generally well, but need time to grow and develop before going home. A recent study suggests that babies born before 26 weeks of pregnancy do better if they are cared for in a NICU. For the next most vulnerable group of premature babies, those born between 27 and 31 weeks of pregnancy, there is no information about whether they would benefit from being looked after in one type of unit or another. The aim of this study is to find out which type of unit leads to the best outcome for babies born at each week of pregnancy in this range is most cost-effective for families and the NHS and best considers views and needs of parents and staff caring for babies.

Who can participate?
Babies born at 27-31 weeks who have been admitted into neonatal units and their parents

What does the study involve?
Babies born between 01/01/2014 and 31/12/2017 are identified using a research database and have information collected about how often they were in hospital during their first year of life is collected. The different types of care offered in LNUs and NICUs to these babies is also reviewed to see if there is a link between the unit they receive care in and their health. The costs of receiving care in the different units are also recorded. Forty parents of premature babies who receive care in these units are also contacted and interviewed to find out their views on the care

given to their children. The information collected throughout the study is then used to work out which is the best type of unit to provide care to these children.

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?
1. New Cross Hospital (UK)
2. Chelsea and Westminster Hospital (UK)
3. Leicester Royal Infirmary (UK)
4. University of Leicester (UK)

When is the study starting and how long is it expected to run for?
February 2017 to August 2022

Who is funding the study?
Health Services and Delivery Research Programme (UK)

Who is the main contact?
Prof Thillagavathie Pillay
tilly.pillay@nhs.net

Study website
https://www.npeu.ox.ac.uk/research/projects/165-opti-prem-improving-neonatal-service-delivery; https://www.royalwolverhampton.nhs.uk/privacy-notice/research/opti-prem.html

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number
212034

ClinicalTrials.gov number
NCT02994849

Secondary identifying numbers
2016NEO87

Study information

Scientific Title
OPTImising neonatal service provision for Preterm babies born between 27 and 31 weeks of gestation using national data, qualitative research and economic analysis

Acronym
OPTI-PREM

Study objectives
The aim of this study is to improve neonatal service delivery for babies born between 27 and 31 weeks of gestation in England, by providing evidence-based data for the development of national policy, on the optimal place of care for such babies.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 17/03/2017, North East Tyne & Wear South Research Ethics Committee (NHSBT Newcastle Blood Donor Centre, Holland Drive, Newcastle upon Tyne, NE2 4NQ, United Kingdom; +44 (0)2071048120, (0)207 104 8286; tyneandwearsouth.rec@hra.nhs.uk), ref: 17/NE/0080

Study design
Multi-centre mixed-methods longitudinal study

Primary study design
Observational

Secondary study design
Longitudinal study

Study setting(s)
Hospital

Study type(s)
Other

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
Neonatal care

Interventions
This study will be conducted in 5 work streams.

Work stream 1:
Statistical analysis of outcomes based on place of care: Babies born between 01/01/2014 and 31/12/2017 will be identified from the NNRD, The National Neonatal Research Database through NDAU (an independent academic unit based at the Chelsea and Westminster campus of Imperial College in London). This is an established resource for research and service evaluations to improve newborn care. Anonymised data (clinical care and outcomes up to discharge from neonatal unit) on all babies will be extracted. Outcomes (significant hospitalisations and mortality) up to 1 year of age, through linkages to Hospital episode statistics and Office for National Statistics will be studied.

Work stream 2:
This will look at the differences in types of clinical care offered between LNUs and NICUs, and whether this could be statistically linked to differences in outcomes, analysing the results of a clinical questionnaire administered to all LNUs and NICUs in England. A questionnaire on clinical care packages offered in neonatal units will be devised at the start of the project and sent to each neonatal unit for completion. Once these are returned, the results will be anonymised and analysed to see if there are any differences in outcomes that can be linked to specific differences in clinical care packages used between units.

Work stream 3:
This will look at the health economic cost of care for babies at each week of gestational age between 27-31 weeks for those managed in a LNU vs a NICU, using data from Workstream 1.

Work stream 4:
A group of 40 parents who have/have had a preterm baby born between 27-31 weeks gestation, and relevant clinical team members will be selected for interview at two Neonatal units in the collaborators Trusts. A qualitative assessment will be conducted by a social scientist, and research worker, and parents, carers and staff will be approached for informed consent for this. This limb will be conducted over 18 months and appropriate consents will be obtained for this. Parents and staff will be offered information leaflets. Only those consenting to be observed and interviewed will be recruited.

Work stream 5:
This will involve using the results obtained to help develop national recommendations with BAPM, which will be used to inform policy making for where best to deliver and care for preterm babies in this group in the future. All of the results obtained from workstreams 1-4 will be collated and meetings established between the national advisory body for neonatal care (BAPM) and the Study group, overseen by a Parent Panel. This group will work together to define national recommendations on the best place of care for these babies in England. The recommendations that are developed from BAPM will then be sent on to NHS England, to inform policy making for where best to deliver and care for preterm babies in this group in the future.

The total duration of the project is 3 years

Intervention Type

Behavioural

Primary outcome measure
Mortality is assessed through medical record review continuously until children are 1 year old.

Secondary outcome measures
1. Clinical care packages at neonatal units is assessed through clinical questionnaire study created for the purpose of this study at 12 months
2. Cost of care for preterm babies is assessed through health economic calculations for hospitalisation for each baby until the child is 1 year old
3. Parent perspectives of care are assessed using a questionnaire designed for the purpose of this study at baseline and for 18 months

Overall study start date
27/02/2017

Completion date
31/08/2022

Eligibility

Key inclusion criteria
1. All babies born at 27-31 weeks of gestation
2. Admitted into neonatal units
3. Records are captured on the National Neonatal Research Database will be included for the study period between 01/01/2014 and 31/12/2017

Participant type(s)
Mixed

Age group
Neonate

Sex
Both

Target number of participants
24,000

Total final enrolment
18847

Key exclusion criteria
Those who elect to opt-out of this project

Date of first enrolment
01/04/2017

Date of final enrolment
01/04/2018

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
New Cross Hospital
Wednesfield Road
Wolverhampton
United Kingdom
WV10 0QP

Study participating centre
Chelsea and Westminster Hospital
369 Fulham Road
London
United Kingdom
SW10 9NH

Study participating centre
Leicester Royal Infirmary
Infirmary Square
Leicester
United Kingdom
LE1 5WW

Study participating centre
University of Leicester
Department of Health Sciences
Centre for Medicine
University Road
Leicester
United Kingdom
LE1 7RH

Study participating centre
University of Oxford
Nuffield Department of Population Health

Oxford
United Kingdom
OX3 7LF

Sponsor information

Organisation
The Royal Wolverhampton NHS Trust

Sponsor details
New Cross Hospital
Wolverhampton
England
United Kingdom
WV10 0QP

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/05pjd0m90

Funder(s)

Funder type
Government

Funder Name
Health Services and Delivery Research Programme

Alternative Name(s)
Health Services and Delivery Research (HS&DR) Programme, NIHR Health Services and Delivery Research (HS&DR) Programme, NIHR Health Services and Delivery Research Programme, HS&DR Programme, HS&DR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Planned publication in high-impact peer reviewed journals with intent to publish date around one year overall trial end date.

Intention to publish date
30/06/2022

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from tilly.pillay@nhs.net and Sarah.glover7@nhs.net

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	22/08/2019	03/09/2020	Yes	No
HRA research summary			28/06/2023	No	No
Results article		27/12/2024	30/12/2024	Yes	No
Results article		01/04/2025	16/04/2025	Yes	No
Abstract results	Cost-Effectiveness	31/12/2024	23/04/2025	No	No
Other publications	Uses qualitative data from the OPTI-PREM study to explore the significant efforts required in practice to accomplish neonatal transfers	26/05/2023	23/04/2025	Yes	No
Plain English results			23/04/2025	No	Yes
Results article	Embedded qualitative study of parents' experiences of neonatal care	18/12/2023	23/04/2025	Yes	No
Results article	Embedded qualitative work exploring neonatal care for babies born 27–31 weeks	27/06/2022	23/04/2025	Yes	No
Results article	Retrospective analysis of resource use data recorded within the National Neonatal Research Database	02/05/2023	23/04/2025	Yes	No