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PCN-CRP: a programme for improving the prediction and prevention of preterm birth and women's experience of care

Submission date
18/09/2025

Recruitment status
Not yet recruiting

Registration date
19/09/2025

Overall study status
Ongoing

Last Edited
19/09/2025

Condition category
Pregnancy and Childbirth

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

Plain English summary of protocol

Background and study aims
Preterm birth is the leading cause of neonatal death and morbidity worldwide. This has significant repercussions for individuals and their families and the economic costs to society are considerable. The Preterm Clinical Network Cohort Research Programme (PCN-CRP) is a series of studies aiming to reduce preterm birth and the problems it can cause. These studies will investigate tests to predict preterm birth, treatments to prevent it, and how to improve outcomes for babies and women's experience of care.

Who can participate?
Pregnant women aged 16 years or above who are at risk of preterm birth, either because they have known risk factors, e.g. have had an early baby before, or those who are experiencing symptoms of threatened preterm labour.

What does the study involve?
Participants will be asked to agree to information being collected from their maternity record. This will include information about the participant (e.g. age, ethnicity), any previous pregnancies or medical conditions, the care received in this pregnancy and the pregnancy outcomes, e.g. whether or not she has her baby early.

What are the possible benefits and risks of participating?
Taking part in this programme is unlikely to have direct benefit for the participant or her current pregnancy. What we learn, however, might help us to improve care for her in any future pregnancies as well as for other women, and reduce the number of babies being born too early. The participant's care will not be affected by taking part and no treatments are being tested so there are no risks or disadvantages, other than the time required to read the information sheet /s and sign the consent form/s.

Where is the study run from?
King's College London and Guy's & St Thomas' NHS Foundation Trust (UK)

When is the study starting and how long is it expected to run for?
April 2024 to March 2028

Who is funding the study?
Tommy’s (the pregnancy and baby charity) (UK)

Who is the main contact?
Dr Jenny Carter, jenny.carter@kcl.ac.uk

Study website
https://www.medscinet.net/ukpcn

Contact information

Type(s)
Public, Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
344400

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
CPMS 65239

Study information

Scientific Title
Preterm Clinical Network Cohort Research Programme (PCN-CRP)

Acronym
PCN-CRP

Study objectives
The Preterm Clinical Network Cohort Research Programme (PCN-CRP) is a series of studies aiming to reduce preterm birth and the problems it can cause. These studies will investigate tests to predict preterm birth, treatments to prevent it, and how to improve outcomes for babies and women's experience of care. The programme will be carried out in partnership with Tommy's National Centre for Preterm Birth Research and the UK Preterm Clinical Network (UKPCN). This is a network of doctors, midwives and scientists who are working together to prevent the problems associated with preterm birth.

Women at risk of preterm birth will be asked to take part in one or more of the programme's individual studies (sub-studies). Although more sub-studies will be added in the future, the first four will investigate:
1. How urine infection affects the chances of preterm birth
2. Whether different characteristics (e.g. position and measurements) of previous caesarean section scars, seen by ultrasound, can help to predict the chances of preterm birth and which treatments would work best
3. How many women at risk of preterm birth suffer from poor mental health, what additional support they are offered and whether they accept it
4. New factors to include in QUiPP, a preterm birth prediction and decision support tool.

Ethics approval required
Ethics approval required

Ethics approval(s)

Approved 17/03/2025, Yorkshire & The Humber - Leeds West Research Ethics Committee (NHSBT Newcastle Blood Donor Centre, Holland Drive, Newcastle upon Tyne, NE2 4NQ, United Kingdom; +44 (0)207 972 25 04; leedswest.rec@hra.nhs.uk), ref: 25/YH/0008

Study design
Multi-centre prospective cohort study

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
Hospital

Study type(s)
Prevention, Screening, Treatment

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

Health condition(s) or problem(s) studied
Prediction and prevention of preterm birth

Interventions
Prospective collection of clinical data for use in sub-studies aiming to improve prediction and prevention of preterm birth.

Following informed consent, data will be collected by attending clinician or research midwives and will include: participant background: demographic characteristics, risk factors, medical and obstetric history; clinical care: preterm surveillance methods and test results, e.g. infection screening, cervical length scan measurements, predictive biomarker tests, mental wellbeing screening tests, concomitant treatments; pregnancy outcomes. Data will be stored on the PCN Database (https://www.medscinet.net/ukpcn). If the participant consents to possible long-term follow-up of her own health or her child's health and developmental status as part of future approved research, this could potentially occur at any time in the future, unless she withdraws her consent.

Intervention Type
Other

Primary outcome measure
The occurrence of mid-trimester pregnancy loss or preterm birth (PTB) before 37 weeks' gestation

Secondary outcome measures
The secondary outcomes that relate to all sub-studies are listed below:
1. Preterm birth before 30 and 34 weeks
2. Mid-trimester loss (14-23 weeks)

3. Gestation at birth
4. Onset of labour (e.g. spontaneous, induced, pre-labour CS)
5. Preterm intervention use (e.g. cerclage, progesterone, vaginal pessary)
6. Antenatal corticosteroid use for fetal lung maturation
7. Magnesium sulphate use for fetal neuroprotection
8. In-utero transfer (for neonatal cot availability)
9. Admission to intensive care unit (mother and neonate)
10. Length of hospital stay (mother and neonate)
11. Infection (mother and neonate)
12. Perinatal death (i.e. stillbirth or neonatal death)
13. Maternal death

Sub-study 1: results of asymptomatic urine screening (dipstick or culture) at booking or first appointment when this is carried out in pregnancy; results of any subsequent urine culture for suspicion of urinary tract infection, with symptoms and treatments will be recorded. This could be at any timepoint in the participant's pregnancy.

Sub-study 2: caesarean section scar characteristics (if seen on transvaginal ultrasound scan) including distance from internal os and dimensions of niche, if observed, will be recorded. This could be at any timepoint in the participant's pregnancy.

Sub-study 3: mental wellbeing will be measured using the validated instruments PHQ9, GAD7, PROMIS-10, at all preterm clinic appointments. This could be at any timepoint in the participant's pregnancy.

Sub-study 4: results of any preterm birth prediction test (including, but not restricted to: vaginal swab tests, such as Actim Partus, transvaginal ultrasound for measurement of cervical length, cervical stiffness measured using the Pregnolia device). This could be at any timepoint in the participant's pregnancy.

Overall study start date
29/04/2024

Completion date
31/03/2028

Eligibility

Key inclusion criteria
Pregnant women will be eligible for the programme if they:
1. Have risk factors for preterm birth: previous preterm or mid-trimester loss, history of invasive cervical surgery, history of in-labour caesarean section, uterine anomaly, any other factor considered a risk factor for preterm birth by clinical expertise or national guidelines, or
2. Are experiencing symptoms of threatened preterm labour
3. Are eligible for at least one of the sub-studies as defined in protocol appendices 21.1-4
4. Are willing and able to give informed consent
5. Are aged 16 years or above

Participant type(s)
Patient, Service user

Age group
Adult

Lower age limit
0 Years

Upper age limit
70 Years

Sex
Female

Target number of participants
13027

Key exclusion criteria
1. Under 16 years old
2. Unwilling to give informed consent

Date of first enrolment
22/09/2025

Date of final enrolment
31/03/2028

Locations

Countries of recruitment
England

Northern Ireland

Scotland

United Kingdom

Wales

Study participating centre
Guy's and St Thomas' NHS Foundation Trust
St Thomas' Hospital
Westminster Bridge Road
London
United Kingdom
SE1 7EH

Study participating centre

University College Hospital Elizabeth Garrett Anderson Wing
235 Euston Road
London
United Kingdom
NW1 2BU

Study participating centre
Doncaster and Bassetlaw Teaching Hospitals NHS Foundation Trust
Doncaster Royal Infirmary
Armthorpe Road
Doncaster
United Kingdom
DN2 5LT

Study participating centre
Barts Health NHS Trust
The Royal London Hospital
80 Newark Street
London
United Kingdom
E1 2ES

Study participating centre
University Hospitals Bristol and Weston NHS Foundation Trust
Trust Headquarters
Marlborough Street
Bristol
United Kingdom
BS1 3NU

Study participating centre
University Hospitals Coventry and Warwickshire NHS Trust
Walsgrave General Hospital
Clifford Bridge Road
Coventry
United Kingdom
CV2 2DX

Study participating centre
University Hospitals Dorset NHS Foundation Trust
Management Offices

Poole Hospital
Longfleet Road
Poole
United Kingdom
BH15 2JB

Study participating centre
Royal Free London NHS Foundation Trust
Royal Free Hospital
Pond Street
London
United Kingdom
NW3 2QG

Study participating centre
Manchester University Hospital NHS Ft (hq)
Oxford Road
Manchester
United Kingdom
M13 9WL

Study participating centre
Swansea Bay University Local Health Board
Tonna Hospital
Tonna Uchaf
Tonna
Neath
United Kingdom
SA11 3LX

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

Study participating centre
Bolton NHS Foundation Trust
The Royal Bolton Hospital

Minerva Road
Farnworth
Bolton
United Kingdom
BL4 0JR

Study participating centre
Birmingham Women's and Children's NHS Foundation Trust
Steelhouse Lane
Birmingham
United Kingdom
B4 6NH

Study participating centre
Leeds Teaching Hospitals NHS Trust
St. James's University Hospital
Beckett Street
Leeds
United Kingdom
LS9 7TF

Study participating centre
Belfast Health and Social Care Trust
Trust Headquarters
A Floor - Belfast City Hospital
Lisburn Road
Belfast
United Kingdom
BT9 7AB

Study participating centre
East Sussex Healthcare NHS Trust Hq
St. Annes House
729 the Ridge
St. Leonards-on-sea
United Kingdom
TN37 7PT

Study participating centre
Fife
Victoria Hospital

Hayfield Road
Kirkcaldy
United Kingdom
KY2 5AH

Study participating centre
Liverpool Women's NHS Foundation Trust
Liverpool Womens Hospital
Crown Street
Liverpool
United Kingdom
L8 7SS

Study participating centre
Countess of Chester Hospital NHS Foundation Trust
Countess of Chester Health Park
Liverpool Road
Chester
United Kingdom
CH2 1UL

Study participating centre
Northern Care Alliance NHS Foundation Trust
Salford Royal
Stott Lane
Salford
United Kingdom
M6 8HD

Study participating centre
East Kent Hospitals University NHS Foundation Trust
Kent & Canterbury Hospital
Ethelbert Road
Canterbury
United Kingdom
CT1 3NG

Study participating centre
Hull University Teaching Hospitals NHS Trust
Hull Royal Infirmary
Anlaby Road

Hull
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HU3 2JZ

Study participating centre
University Hospitals Birmingham NHS Foundation Trust
Queen Elizabeth Hospital
Mindelsohn Way
Edgbaston
Birmingham
United Kingdom
B15 2GW

Study participating centre
Somerset NHS Foundation Trust
Trust Management
Lydeard House
Musgrove Park Hospital
Taunton
United Kingdom
TA1 5DA

Study participating centre
Cambridge University Hospitals NHS Foundation Trust
Cambridge Biomedical Campus
Hills Road
Cambridge
United Kingdom
CB2 0QQ

Study participating centre
James Paget University Hospitals NHS Foundation Trust
Lowestoft Road
Gorleston
Great Yarmouth
United Kingdom
NR31 6LA

Study participating centre
York and Scarborough Teaching Hospitals NHS Foundation Trust
York Hospital

Wigginton Road
York
United Kingdom
YO31 8HE

Study participating centre
Lewisham and Greenwich NHS Trust
University Hospital Lewisham
Lewisham High Street
London
United Kingdom
SE13 6LH

Study participating centre
North Cumbria Integrated Care NHS Foundation Trust
Pillars Building
Cumberland Infirmary
Infirmary Street
Carlisle
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CA2 7HY

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vpri@kcl.ac.uk

Sponsor type
University/education

Website
kcl.ac.uk

Organisation
Guy's & St Thomas' NHS Foundation Trust

Sponsor details
R&D Office
16th Floor Tower Block
Guy’s Hospital
London
England
United Kingdom
SE1 9RT
+44 (0)20 7188 7188, ext 54426
gstt.randd@nhs.net

Sponsor type
Hospital/treatment centre

Website
https://www.guysandstthomas.nhs.uk/

Funder(s)

Funder type
Charity

Funder Name
Tommy's

Results and Publications

Publication and dissemination plan
Findings will be shared through medical literature, as well as the wider media and PPI social networks, and ultimately will inform further research and national clinical guidelines.

Intention to publish date
31/03/2029

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be available upon request.

Where participants have explicitly consented to their data being shared for future research purposes, anonymised data may be shared with third party researchers subject to review and

approval of the Preterm Clinical Network (PCN) Database Access Committee. This committee comprises clinical preterm birth expert members of the UK Preterm Clinical Network and a patient representative with lived experience. The committee is governed by procedures stipulated in the PCN Database protocol and approved by Research Ethics Committee (REC 22/ES /0001; IRAS 308157). These include submission of detailed application form by third party researchers and committee review of research team and project. If approved, anonymised data is transferred by secure means following execution of data sharing agreements between parties (i.e. KCL, researcher institution and contributing Data Collection Centres).

IPD sharing plan summary

Available on request