

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 Recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 19/09/2025	Overall study status Ongoing	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 19/09/2025	Condition category Pregnancy and Childbirth	<input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> 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

Contact information

Type(s)

Public, Scientific

Contact name

Dr Jenny Carter

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Principal investigator

Contact name

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Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

Integrated Research Application System (IRAS)

344400

ClinicalTrials.gov (NCT)

Nil known

Protocol serial number

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

Study type(s)

Prevention, Screening, Treatment

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(s)

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

Key secondary outcome(s)

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.

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

0 years

Upper age limit

70 years

Sex

Female

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

United Kingdom

England

Northern Ireland

Scotland

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
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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

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Liverpool Road

Chester

United Kingdom

CH2 1UL

Study participating centre

Northern Care Alliance NHS Foundation Trust

Salford Royal

Stott Lane

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Study participating centre

East Kent Hospitals University NHS Foundation Trust

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CT1 3NG

Study participating centre

Hull University Teaching Hospitals NHS Trust

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University Hospitals Birmingham NHS Foundation Trust

Queen Elizabeth Hospital

Mindelsohn Way

Edgbaston

Birmingham

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B15 2GW

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Somerset NHS Foundation Trust
Trust Management
Lydeard House
Musgrove Park Hospital
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TA1 5DA

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Cambridge Biomedical Campus
Hills Road
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CB2 0QQ

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

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York
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YO31 8HE

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

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

Sponsor information

Organisation
King's College London

Organisation
Guy's & St Thomas' NHS Foundation Trust

Funder(s)

Funder type
Charity

Funder Name
Tommy's

Results and Publications

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Study website	Study website	11/11/2025	11/11/2025	No	Yes