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The POOL study: establishing the safety of waterbirth for mothers and babies

Submission date
18/04/2018

Recruitment status
No longer recruiting

Registration date
04/05/2018

Overall study status
Completed

Last Edited
06/06/2025

Condition category
Pregnancy and Childbirth

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

Plain English summary of protocol

Background and study aims
It is estimated that up to 60,000 (9 in every 100) babies are born into water annually in the UK and with encouragement from NICE for maternity units to provide birthing pools for women, this number may increase further. Women use a birth pool during labour for pain relief, and some women choose to remain in the pool for the birth of their baby. Over the years there have been reports of babies that had breathing difficulties or infection following birth in water, and there is a concern that women that have a waterbirth more often sustain severe trauma to their vaginal area or have unrecognised heavy bleeding. Despite concern and some reports in the press, to date, there have not been studies large enough to show whether or not waterbirth causes an increase in these poor outcomes for mothers or their babies. This study aims to find out whether waterbirth is as safe for mothers and babies as leaving the pool before birth.

Who can participate?
Women who meet NICE criteria for 'low risk' and who use a pool (water immersion) during labour

What does the study involve?
The study collects data on the births of all women in around 26 maternity units during 2015-2022 (updated 09/09/2022, previously 30 maternity units during 2015-2020) to see how many women are using birth pools, how many women give birth in water and whether mothers or their babies come to any extra harm as a result of waterbirth. The study includes women giving birth to their first baby and women giving birth to a subsequent child. The study needs to collect information on 15,000 water births and 15,000 births out of water. To do this without disturbing women in labour or just after birth, when they are looking after their new baby, the study uses information collected as part of each woman's and linked baby's maternity record stored at hospitals in computerised systems. For babies who need specialist care after birth, the study also uses data held by the National Neonatal Research Database. Some of the data needed for this study is already collected by maternity units, so data from births from 2015 onwards can be included in the study. However, as some important information needed to fully answer the study questions, such as how many babies have antibiotics, and how many women deliver the placenta underwater, is currently not collected, some new items are added to maternity computer systems when the study starts in 2018. To keep women's information confidential, the data stored in existing maternity information systems has the identifying information, such as names,

addresses and NHS numbers, removed before the information is sent to the research team in Cardiff for analysis.

What are the possible benefits and risks of participating?
The study will produce academic papers and evidence-based information for women and their partners on waterbirth. The study findings will be of great interest and are expected to generate much press interest, and quickly influence the information provided to pregnant women throughout the UK. The benefit of participating is minimal to the individual but will be contributing to research. The main advantage is that the participant will be able to share experiences to help improve understanding of the factors that influence the use of birth pools and giving birth in water. This study has been identified as low risk, and no higher than the risk of standard medical care. Participation in the discussion group is not likely to involve any particular risks although it may bring back memories of difficult or distressing experiences. The main disadvantage for the participant is giving up their time to join in the discussion.

Where is the study run from?
University Hospital Wales (UK)

When is the study starting and how long is it expected to run for?
April 2018 to March 2024

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

Who is the main contact?
Rebecca Milton, miltonrl1@cardiff.ac.uk
Julia Sanders, sandersj3@cardiff.ac.uk

Study website
https://www.journalslibrary.nihr.ac.uk/programmes/hta/1614901/#/

Contact information

Type(s)
Public

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
HTA 16/149/01

Study information

Scientific Title
Establishing the safety of waterbirth for mothers and babies: a cohort study with nested qualitative component

Acronym
POOL

Study objectives
To establish whether for 'low-risk' women who use a pool during labour, waterbirth, compared to leaving a pool prior to birth, is as safe for mothers and babies.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 09/10/2018, Wales Research Ethics Committee (Wales REC 3) (Castlebridge 4, 15 – 19 Cowbridge Road East, Health and Care Research Wales, CF11 9AB, United Kingdom; +44(0)2920 785739; wales.rec3@wales.nhs.uk), ref: 18/WA/0291

Study design

Cohort study with a nested qualitative component, using a combination of data captured retrospectively and prospectively (January 2015 to June 2022) in electronic NHS maternity and neonatal information systems

Primary study design
Observational

Secondary study design
Cohort 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
Birth in water following water immersion during labour

Interventions
Current interventions as of 09/09/2022:
Summary of methodology: A natural experiment using a cohort design with a nested qualitative component will answer the study objectives by using a combination of data captured retrospectively and prospectively in electronic NHS maternity and neonatal information systems. The qualitative component will explore factors associated with high and low rates of pool use; data will be gathered in online discussion groups, focus groups and one-to-one interviews with key stakeholders, including women.

To answer all research objectives approximately 600,000 individual computerised maternity records held on secure NHS servers at around 30 NHS sites, covering the period January 2015 – June 2022 will be accessed. To provide necessary denominator data, and to be able to compare characteristics of pool users and non-pool users, a minimal data set will be extracted relating to women who did not use a pool in labour, whilst a more extensive dataset will be extracted for women who did use a pool in labour. An important clinical question is whether there is a differential effect of waterbirth on severe perineal trauma (OASIS) amongst nulliparous and parous women. To undertake this subgroup analysis will require a necessarily large sample (30,000). As data relating to perineal trauma and waterbirth are already captured, and to avoid unnecessarily prolongation of the study, this analysis will use a combination of retrospective and prospectively collected data, including births from 2015 to 2022.

The sample required for the neonatal primary outcome is smaller (16,200) and, as all essential data are not currently collected for one component of this composite outcome (antibiotic administration within 48 hours of birth on postnatal wards) additional data fields will be added to maternity systems at participating NHS sites. Therefore, we will collect these data on births prospectively during the period from site opening (c. January 2019 onwards to 30th June 2022 /site closure).

Some neonatal outcomes of interest, including neonatal hypoxia, respiratory support or neonatal mortality, are already held by study sites or by the National Neonatal Research Database (NNRD). Where available and where the risk status and pool usage of mothers can be determined, retrospective data will be utilised to increase the power of the analysis around secondary neonatal outcomes.

The NNRD holds individual patient-level data on all babies admitted for National Health Service (NHS) neonatal care in England, Scotland and Wales from 2014 to the present. To obtain detailed treatment and outcome information on any baby who required admission to a neonatal unit, following their mother's pool use in labour, the identifiers of all babies born to women who used a pool during the period of prospective data collection will be extracted and matched to any records held by the NNRD.

The primary study aim is to compare maternal and neonatal outcomes for 'low risk' women who gave birth in the water against 'low risk' women who left the water prior to birth.

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Previous interventions:
A natural experiment using a cohort design with a nested qualitative component will answer the study objectives by using a combination of data captured retrospectively and prospectively in electronic NHS maternity and neonatal information systems. The qualitative component will explore factors associated with high and low rates of pool use; data will be gathered in online discussion groups, focus groups and one-to-one interviews with key stakeholders, including women.

To answer all research objectives approximately 600,000 individual computerised maternity records held on secure NHS servers at around 30 NHS sites, covering the period January 2015 – November 2020 will be accessed. To provide necessary denominator data, and to be able to compare characteristics of pool users and non-pool users, a minimal data set will be extracted relating to women who did not use a pool in labour, whilst a more extensive dataset will be extracted for women who did use a pool in labour. An important clinical question is whether there is a differential effect of waterbirth on severe perineal trauma (OASIS) amongst nulliparous and parous women. To undertake this subgroup analysis will require a necessarily large sample (30,000). As data relating to perineal trauma and waterbirth are already captured, and to avoid unnecessarily prolongation of the study, this analysis will use a combination of retrospective and prospectively collected data, including births from 2015 to 2020.

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Some neonatal outcomes of interest, including neonatal hypoxia, respiratory support or neonatal mortality, are already held by study sites or by the National Neonatal Research Database (NNRD). Where available and where the risk status, and pool usage of mothers can be determined, retrospective data will be utilised to increase the power of the analysis around secondary neonatal outcomes.

The NNRD holds individual patient level data on all babies admitted for National Health Service (NHS) neonatal care in England, Scotland and Wales from 2014 to present. To obtain detailed treatment and outcome information on any baby who required admission to a neonatal unit,

following their mother's pool use in labour, the identifiers of all babies born to women who used a pool during the period of prospective data collection will be extracted and matched to any records held by the NNRD.

The primary study aim is to compare maternal and neonatal outcomes for 'low risk' women who gave birth in water against 'low risk' women who left the water prior to birth.

Intervention Type
Other

Primary outcome measure
Maternal primary outcome measure:
Obstetric Anal Sphincter Injuries (OASIS), measured using routinely collected maternal data (EUROKING) at birth

Neonatal primary outcome measure:
Composite outcome of 'adverse neonatal outcomes or treatment:
1. Any neonatal unit admission requiring respiratory support, measured using routinely collected neonatal data (NNRD) at hospital discharge
2. Antibiotic administration within 48 hours of birth (with or without culture proven infection), measured using routinely collected maternal data (EUROKING) at hospital discharge
3. Intrapartum stillbirth or neonatal death, measured using routinely collected maternal data (EUROKING) at hospital discharge

Secondary outcome measures
Current secondary outcome measures as of 09/09/2022:
Maternal secondary outcome measures:
1. Maternal intrapartum: shoulder dystocia and required management, management of the third stage of labour, need and reason for obstetric involvement in woman's care, maternal position at birth, treatment for haemorrhage, incidence and management of perineal and other genital trauma. Measured using routinely collected maternity data (EUROKING) at birth.
2. Maternal postnatal: duration of postnatal stay, breastfeeding initiation and continuation, higher level care, and maternal readmission to the hospital within 7 days of birth. Measured using routinely collected maternity data (EUROKING) at hospital discharge.
3. Lumbar puncture, culture-proven infection, brachial plexus injury, treatment for jaundice, therapeutic hypothermia, measured using routinely collected maternity data (EUROKING) at hospital discharge

Infant secondary outcome measures:
1. Timing of cord clamping measured using routinely collected maternity data (EUROKING) at birth
2. Apgar scores measured using routinely collected maternity data (EUROKING) at birth
3. Resuscitation measured using routinely collected maternity data (EUROKING) at birth
4. Intrapartum stillbirth or all deaths prior to neonatal unit/postnatal ward discharge measured using routinely collected neonatal and maternity data (NNRD, EUROKING) at birth and hospital discharge
5. Neonatal deaths that occurred within seven days of birth on a neonatal unit/postnatal ward measured using routinely collected maternity data (EUROKING) at birth, during admission or during readmission
6. Snapped umbilical cord prior to clamping measured using routinely collected maternity data (EUROKING) at birth

7. Skin-to-skin contact at birth measured using routinely collected maternity data (EUROKING) at birth
8. First breastfeed within the first hour measured using routinely collected maternity data (EUROKING) at birth
9. Administration of intravenous antibiotics including timing and duration measured using POOL specific and routinely collected neonatal data (NNRD, EUROKING) at hospital discharge
10. Blood culture positive with a recognised pathogen (excluding skin commensal organisms) measured using POOL specific and routinely collected neonatal data (NNRD, EUROKING) at hospital discharge
11. Highest CRP results measured using POOL-specific and routinely collected neonatal and maternity data (EUROKING) at hospital discharge
12. Successful / attempted lumbar puncture measured using routinely collected maternity data (EUROKING) at hospital discharge
13. Neonatal unit admissions measured using routinely collected maternity and neonatal data (EUROKING, NNRD)
14. Respiratory support measured using routinely collected neonatal (NNRD) at hospital discharge
15. Therapeutic hypothermia measured using routinely collected neonatal data (NNRD) at hospital discharge
16. Birth injuries measured using routinely collected maternity and neonatal data (EUROKING, NNRD) at hospital discharge
17. Treatment for jaundice measured using routinely collected maternity and neonatal data (EUROKING, NNRD) at hospital discharge
18. Readmission to the hospital within seven days of birth measured using routinely collected maternity data (EUROKING) at readmission

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Previous secondary outcome measures:
Maternal secondary outcome measures:
1. Maternal intrapartum: Shoulder dystocia and required management, management of the third stage of labour, need and reason for obstetric involvement in woman's care including sepsis; mode of birth, maternal position at birth, treatment for haemorrhage, incidence and management of perineal and other genital trauma. Measured using routinely collected maternal data (EUROKING) at birth
2. Maternal postnatal: duration of postnatal stay, breastfeeding initiation and continuation, higher level care, and maternal readmission to hospital within 7 days of birth. Measured using routinely collected maternal data (EUROKING) at hospital discharge

Infant secondary outcome measures:
1. Snapped umbilical cord prior to clamping, skin to skin contact at birth, timing of cord clamping, resuscitation , Apgar scores. Measured using routinely collected maternal data (EUROKING) at birth
2. Administration and duration of intravenous antibiotics, measured using routinely collected maternal data (EUROKING) at hospital discharge
3. Lumbar puncture, culture proven infection, brachial plexus injury, treatment for jaundice, therapeutic hypothermia, measured using routinely collected maternal data (EUROKING) at hospital discharge
4. Neonatal unit admission and duration, cause of neonatal death, respiratory support, measured using routinely collected neonatal and maternal data (NNRD, EUROKING) at hospital discharge
5. Readmission to hospital within 7 days of birth, measured using routinely collected maternal data (EUROKING) at readmission

Overall study start date
01/04/2018

Completion date
31/03/2024

Eligibility

Key inclusion criteria
Current participant inclusion criteria as of 09/09/2022:
1. Women, and their infants, if the woman used water immersion at a study site during the period of data collection
2. Any women for whom water immersion analgesia is recorded in Wellbeing Software's E3 system
3. Birth in which the foetus is partially or totally expelled under water

Previous participant inclusion criteria:
Routine Data Work Package: Women who meet NICE criteria for 'low risk' and who use a pool (water immersion) during labour

Qualitative Work Package: [online stakeholder discussion groups]
1. Heads of Midwifery / Midwifery Managers from study sites
2. Consultant Midwives from study sites
3. Band 5/6 clinically focused midwives
4. UK Obstetricians from within and outside of study sites (accessed via RCOG or another route)
5. UK Neonatologists from within and outside of study sites (accessed via the UK Neonatal Collaborative (UKNC) the RCPCH or another route
6. Public including members of the RCOG Women's group, with participation open to women at study and non-study sites

Participant type(s)
Mixed

Age group
Mixed

Sex
Both

Target number of participants
600,000 computerised maternity records. Routine Data Work Package: 30,000 mothers. 16,200 neonates. Qualitative Work Package: Six closed online stakeholder discussion groups will be conducted, including the following participants: 1. Heads of Midwifery / Midwifery Managers from study sites. 2. Consultant Midwives from study sites. 3. Band 5/6 clinically focused midwives. 4. UK Obstetricians from within and outside of study sites (accessed via RCOG or another route). 5. UK Neonatologists from within and outside of study sites (accessed via the UK Neonatal Collaborative (UKNC) the RCPCH or another route. 6. Public including members of the RCOG Women's group, with participation open to women at study and non-study sites.

Total final enrolment

52410

Key exclusion criteria
Excluded from data analysis: Data relating to women and babies recorded in EuroKing as being ‘Born Before Arrival’ (BBA), or recorded as intentionally born without midwifery attendance, will be excluded from primary analysis as well as those who opt-out from the study

Date of first enrolment
01/06/2018

Date of final enrolment
30/06/2022

Locations

Countries of recruitment
United Kingdom

Wales

Study participating centre
University Hospital Wales
Heath Park
Cardiff
United Kingdom
CF14 4YS

Study participating centre
Salisbury District Hospital
Salisbury District Hospital
Odstock Road
Salisbury
United Kingdom
SP2 8BJ

Study participating centre
Barking, Havering and Redbridge University Hospitals NHS Trust
Queens Hospital
Rom Valley Way
Romford
United Kingdom
RM7 0AG

Study participating centre
Victoria Hospital (blackpool)
Whinney Heys Road
Blackpool
United Kingdom
FY3 8NR

Study participating centre
Bolton Royal Hospital
Minerva Road
Farnworth
Bolton
United Kingdom
BL4 0JR

Study participating centre
Darent Valley Hospital
Darenth Wood Road
Dartford
United Kingdom
DA2 8DA

Study participating centre
William Harvey Hospital
Kennington Road
Willesborough
Ashford
United Kingdom
TN24 0LZ

Study participating centre
Queen Elizabeth the Queen Mother Hospital
St. Peters Road
Margate
United Kingdom
CT9 4AN

Study participating centre
Frimley Park Hospital Liaison Office
Portsmouth Road
Frimley

Camberley
United Kingdom
GU16 7UJ

Study participating centre
The Hillingdon Hospital
Pield Heath Road
Uxbridge
United Kingdom
UB8 3NN

Study participating centre
St Marys Hospital
St. Marys Hospital
Parkhurst Road
Newport
United Kingdom
PO30 5TG

Study participating centre
West Suffolk NHS Foundation Trust
West Suffolk Hospital
Hardwick Lane
Bury St. Edmunds
United Kingdom
IP33 2QZ

Study participating centre
James Paget University Hospital
Lowestoft Road
Gorleston
Great Yarmouth
United Kingdom
NR31 6LA

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

Study participating centre
Wythenshawe Hospital
Southmoor Road
Wythenshawe
Manchester
United Kingdom
M23 9LT

Study participating centre
North Manchester General Hospital
Delaunays Road
Crumpsall
Manchester
United Kingdom
M8 5RB

Study participating centre
Medway Maritime Hospital
Windmill Road
Gillingham
United Kingdom
ME7 5NY

Study participating centre
Royal Victoria Infirmary
Claremont Wing Eye Dept
Royal Victoria Infirmary
Queen Victoria Road
Newcastle upon Tyne
United Kingdom
NE1 4LP

Study participating centre
Southmead Hospital
Southmead Road
Westbury-on-trym
Bristol
United Kingdom
BS10 5NB

Study participating centre
Northumbria Healthcare NHS Foundation Trust
North Tyneside General Hospital
Rake Lane
North Shields
United Kingdom
NE29 8NH

Study participating centre
The Royal Oldham Hospital
Rochdale Road
Oldham
United Kingdom
OL1 2JH

Study participating centre
Royal Cornwall Hospital (treliske)
Treliske
Truro
United Kingdom
TR1 3LJ

Study participating centre
The James Cook University Hospital
Marton Road
Middlesbrough
United Kingdom
TS4 3BW

Study participating centre
Stepping Hill Hospital
Stockport NHS Foundation Trust
Poplar Grove
Hazel Grove
Stockport
United Kingdom
SK2 7JE

Study participating centre

Wrightington Hospital
Hall Lane
Appley Bridge
Wigan
United Kingdom
WN6 9EP

Study participating centre
Smcs at St Georges Hospital
St Georges Hospital
Blackshaw Road
London
United Kingdom
SW17 0QT

Study participating centre
Norfolk and Norwich University Hospital
Colney Lane
Colney
Norwich
United Kingdom
NR4 7UY

Study participating centre
Maidstone
Maidstone Hospital
Hermitage Lane
Maidstone
United Kingdom
ME16 9QQ

Study participating centre
Tunbridge Wells Hospital
The Tunbridge Wells Hospital
Tonbridge Road
Pembury
Tunbridge Wells
United Kingdom
TN2 4QJ

Sponsor information

Organisation
Cardiff University

Sponsor details
McKenzie House
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United Kingdom
CF24 0DE
+44 (0)29 2087 4000
resgov@cardiff.ac.uk

Sponsor type
University/education

Website
www.cardiff.ac.uk

ROR
https://ror.org/03kk7td41

Funder(s)

Funder type
Government

Funder Name
Health Technology Assessment Programme

Alternative Name(s)
NIHR Health Technology Assessment Programme, HTA

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer reviewed journal.

Intention to publish date
23/06/2024

Individual participant data (IPD) sharing plan
Current IPD sharing statement as of 09/09/2022:
The datasets generated during and/or analysed during the current study are not expected to be made available, for further information please contact SandersJ3@cardiff.ac.uk or roblingmr@cardiff.ac.uk

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Previous IPD sharing statement:
The datasets generated during and/or analysed during the current study are/will be available upon request from Michael Robling (RoblingMR@cardiff.ac.uk).

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	08/01/2021	11/01/2021	Yes	No
Statistical Analysis Plan	version 1.0	30/06/2022	13/06/2023	No	No
HRA research summary			26/07/2023	No	No
Results article	Primary	10/06/2024	16/01/2025	Yes	No
Results article	Characteristics of women, intrapartum interventions, and maternal and neonatal outcomes	12/05/2025	06/06/2025	Yes	No