

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

<b>Submission date</b> 18/04/2018	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 04/05/2018	<b>Overall study status</b> Completed	<input checked="" type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 10/02/2026	<b>Condition category</b> Pregnancy and Childbirth	<input type="checkbox"/> 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

## Contact information

### Type(s)

Public

### Contact name

Miss Rebecca Milton

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### Contact name

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CF14 4YS  
+44 (0)2920 687174  
BarlowC2@cardiff.ac.uk

**Additional identifiers****Protocol serial number**

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

**Study type(s)**

Other

## 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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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(s)**

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

### **Key secondary outcome(s)**

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

**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

**Healthy volunteers allowed**

Yes

**Age group**

Mixed

**Sex**

All

**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

Wales

CF14 4YS

**Study participating centre**

**Salisbury District Hospital**  
Salisbury District Hospital  
Odstock Road  
Salisbury  
England  
SP2 8BJ

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

**Study participating centre**  
**Victoria Hospital (blackpool)**  
Whinney Heys Road  
Blackpool  
England  
FY3 8NR

**Study participating centre**  
**Bolton Royal Hospital**  
Minerva Road  
Farnworth  
Bolton  
England  
BL4 0JR

**Study participating centre**  
**Darent Valley Hospital**  
Darenth Wood Road  
Dartford  
England  
DA2 8DA

**Study participating centre**  
**William Harvey Hospital**  
Kennington Road  
Willesborough

Ashford  
England  
TN24 0LZ

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

**Study participating centre**  
**Frimley Park Hospital Liaison Office**  
Portsmouth Road  
Frimley  
Camberley  
England  
GU16 7UJ

**Study participating centre**  
**The Hillingdon Hospital**  
Pield Heath Road  
Uxbridge  
England  
UB8 3NN

**Study participating centre**  
**St Marys Hospital**  
St. Marys Hospital  
Parkhurst Road  
Newport  
England  
PO30 5TG

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

**Study participating centre**  
**James Paget University Hospital**  
Lowestoft Road  
Gorleston  
Great Yarmouth  
England  
NR31 6LA

**Study participating centre**  
**Leicester Royal Infirmary**  
Infirmary Square  
Leicester  
England  
LE1 5WW

**Study participating centre**  
**Wythenshawe Hospital**  
Southmoor Road  
Wythenshawe  
Manchester  
England  
M23 9LT

**Study participating centre**  
**North Manchester General Hospital**  
Delaunays Road  
Crumpsall  
Manchester  
England  
M8 5RB

**Study participating centre**  
**Medway Maritime Hospital**  
Windmill Road  
Gillingham  
England  
ME7 5NY

**Study participating centre**

**Royal Victoria Infirmary**

Claremont Wing Eye Dept  
Royal Victoria Infirmary  
Queen Victoria Road  
Newcastle upon Tyne  
England  
NE1 4LP

**Study participating centre**

**Southmead Hospital**

Southmead Road  
Westbury-on-trym  
Bristol  
England  
BS10 5NB

**Study participating centre**

**Northumbria Healthcare NHS Foundation Trust**

North Tyneside General Hospital  
Rake Lane  
North Shields  
England  
NE29 8NH

**Study participating centre**

**The Royal Oldham Hospital**

Rochdale Road  
Oldham  
England  
OL1 2JH

**Study participating centre**

**Royal Cornwall Hospital (treliste)**

Treliske  
Truro  
England  
TR1 3LJ

**Study participating centre**

**The James Cook University Hospital**  
Marton Road  
Middlesbrough  
England  
TS4 3BW

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

**Study participating centre**  
**Wrightington Hospital**  
Hall Lane  
Appley Bridge  
Wigan  
England  
WN6 9EP

**Study participating centre**  
**Smcs at St Georges Hospital**  
St Georges Hospital  
Blackshaw Road  
London  
England  
SW17 0QT

**Study participating centre**  
**Norfolk and Norwich University Hospital**  
Colney Lane  
Colney  
Norwich  
England  
NR4 7UY

**Study participating centre**

**Maidstone**

Maidstone Hospital  
Hermitage Lane  
Maidstone  
England  
ME16 9QQ

**Study participating centre**

**Tunbridge Wells Hospital**  
The Tunbridge Wells Hospital  
Tonbridge Road  
Pembury  
Tunbridge Wells  
England  
TN2 4QJ

## Sponsor information

**Organisation**

Cardiff University

**ROR**

<https://ror.org/03kk7td41>

## Funder(s)

**Funder type**

Government

**Funder Name**

Health Technology Assessment Programme

**Alternative Name(s)**

NIHR Health Technology Assessment Programme, Health Technology Assessment (HTA), HTA

**Funding Body Type**

Government organisation

**Funding Body Subtype**

National government

**Location**

## Results and Publications

### Individual participant data (IPD) sharing plan

#### IPD sharing plan summary

Not expected to be made available

#### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>	Primary	10/06/2024	16/01/2025	Yes	No
<a href="#">Results article</a>	Characteristics of women, intrapartum interventions, and maternal and neonatal outcomes	12/05/2025	06/06/2025	Yes	No
<a href="#">Results article</a>	Establishing the safety of waterbirth for mothers and their babies: the POOL cohort study with nested qualitative component	01/02/2026	10/02/2026	Yes	No
<a href="#">Protocol article</a>	protocol	08/01/2021	11/01/2021	Yes	No
<a href="#">HRA research summary</a>			26/07/2023	No	No
<a href="#">Statistical Analysis Plan</a>	version 1.0	30/06/2022	13/06/2023	No	No
<a href="#">Study website</a>	Study website	11/11/2025	11/11/2025	No	Yes