



Extended Research Article

Establishing the safety of waterbirth for mothers and their babies: the POOL cohort study with nested qualitative component

Julia Sanders,^{1*} Christian Barlow,² Peter Brocklehurst,³ Rebecca Cannings-John,² Susan Channon,² Christopher Gale,⁴ Judith Cutter,⁵ Jacqueline Hughes,² Billie Hunter,¹ Fiona Lugg-Widger,² Sarah Milosevic,² Rebecca Milton,² Leah Morantz,⁶ Mary Nolan,⁷ Rachel Plachcinski,⁶ Shantini Paranjothy⁸ and Michael Robling²

¹School of Healthcare Sciences, Cardiff University, Cardiff, UK

²Centre for Trials Research, Cardiff University, Cardiff, UK

³Birmingham Clinical Trials Unit, University of Birmingham, Birmingham, UK

⁴Imperial College London and Chelsea and Westminster NHS Foundation Trust, London, UK

⁵Cardiff & Vale University Health Board, Cardiff, UK

⁶Patient and public involvement representative

⁷University of Worcester, Worcester, UK

⁸University of Aberdeen, Aberdeen, UK

*Corresponding author sandersj3@cardiff.ac.uk

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Scientific summary

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Scientific summary

Objectives

The primary study objective was to establish whether, in the case of 'low-risk' women who use a pool during labour, waterbirth, compared to birth out of water, is as safe for mothers and their babies.

The secondary objectives of the study were to:

- Evaluate if the waterbirth was associated with an increase in adverse infant outcomes or treatment, including asphyxia, infection, respiratory difficulties and mortality; or maternal morbidity, particularly complex perineal trauma [obstetric anal sphincter injuries (OASIs)] and haemorrhage.
- Assess the primary safety outcomes among the subgroups of nulliparous and parous women who were 'low risk' at labour onset.
- Describe rates and treatment of haemorrhage for 'low-risk' women who, following birth in water, deliver the placenta underwater. This was also to be described for women who leave the water prior to delivery of the placenta.

The study also planned to:

- describe the proportion and characteristics of women who used a pool for labour or birth compared to women who do not use a pool
- describe the characteristics of, and outcomes for, women with identified risk factors at labour onset, who used a pool during labour
- describe the characteristics of and outcomes for women who develop labour complications who used a pool during labour, inclusive of labour interventions such as cardiotocograph (CTG) and augmentation with oxytocin.
- explore factors associated with high and low rates of pool use in individual maternity units.

Methods

The POOL Study was a natural experiment using a cohort design with a nested qualitative component. The cohort study used a combination of retrospective and prospective data captured in electronic NHS maternity and neonatal information systems at 26 sites. The qualitative component explored factors influencing pool use and waterbirth through online chat groups, interviews and case studies.

To extract, link and analyse maternity data and data relating to babies who had been admitted to a neonatal unit (NNU), Cardiff University partnered with a maternity information system provider and the National Neonatal Research Database.

Setting

The study was set in 26 NHS maternity services with waterbirth facilities across England and Wales.

Main outcome measures

Maternal primary outcome: OASI (with planned subgroup analysis by parity); neonatal composite primary outcome: fetal or neonatal death (after the commencement of intrapartum care and prior to discharge home), NNU admission with respiratory support or the administration of intravenous antibiotics within 48 hours of birth.

Primary analysis was restricted to births where the woman: (1) was without complicating conditions in her antenatal records or recorded at the time of pool entry, (2) used water immersion during labour and (3) did not receive additional monitoring or interventions before birth. Separate a priori sample size calculations were undertaken for the maternal and neonatal primary outcomes.

Sample size

The non-inferiority of birth in water compared to birth on land on rates of OASI was examined by parity. A sample size of 15,000 nulliparous and 15,000 parous women (7500 each water and land) without antenatal complexities and who did not require additional monitoring or interventions before birth was required to obtain 90% power and a one-sided 95% confidence interval (CI) around a treatment difference of zero. A non-inferiority margin of $\leq 1\%$ [odds ratio (OR) ≤ 1.23], and $\leq 0.6\%$ (OR ≤ 1.38), was taken as clinically non-significant among nulliparous and parous women without antenatal complexities, respectively.

For the infant primary outcome, an estimate of 5% was used for the proportion of infants born to low-risk mothers experiencing 'adverse infant outcome or treatment'. A non-inferiority margin of $\leq 1.0\%$ (OR ≤ 1.21) was taken as clinically non-significant. A sample size of 16,200 infants (8100 per group water/land) was required to have 90% power and a one-sided 95% CI around a treatment difference of zero.

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Participants

All women recorded as having used water immersion during labour or birth during the study period from 1 January 2015 to 30 June 2022 at 26 participating NHS organisations were eligible for inclusion. Water immersion during labour and waterbirths was identified and recorded as part of mandatory record-keeping by the attending midwives, and it included the use of baths, tubs or specialist birthing pools.

All births where care had been provided by the participating NHS organisation were included regardless of birth setting, including in obstetric units (OUs), at home or in midwifery-led units. Stillbirths, with fetal death occurring before the start of care in labour were excluded, as were births where a midwife was not in attendance, either because the women chose to give birth without professional assistance outside of a maternity unit or because of birth occurring at home or elsewhere before professional assistance arrived or could be reached.

Results

After removal of duplicates and ineligible cases, a total of 869,744 birth records were analysed, of which 87,040 (10.0%) included a record of water immersion during labour, including 46,827 (5.4%) waterbirths.

Among women without recorded antenatal risk factors or complicating factors at pool entry, 29% of nulliparous women and 5% of parous women who used a pool during labour received additional monitoring, obstetric interventions or regional analgesia, before or during birth. Among women using a pool during labour, without recorded antenatal risk factors or complicating factors at pool entry, and among nulliparous and parous women, respectively, rates of spontaneous vaginal births were 78.0% and 97.6%; rates of instrumental births were 10.9% and 1.6%; and rates of birth by caesarean section were 5.9% and 0.7%.

After adjusting for differences in the characteristics of women who used intrapartum water immersion and gave birth in or out of water: (1) among nulliparous women, rates of recorded OASI were no higher among women who gave birth in water than among women who left the pool before birth [730 of 15,176 women (4.8%) vs. 641 of 12,210 women (5.3%); adjusted odds ratio (aOR) 0.97; one-sided 95% CI, $-\infty$ to 1.08]; (2) among parous women, rates of recorded OASI were no higher among women who gave birth in water than among women who left the pool before birth [269 of 24,451 women (1.1%) vs. 144 of 8565 women (1.7%); aOR 0.64; $-\infty$ to 0.78] and (3) among babies, rates of the primary outcome were no higher among babies born in water than among babies born out of water [263 of 9868 infants (2.7%) vs. 224 of 5078 infants (4.4%); aOR, 0.65; $-\infty$ to 0.79].

All upper CIs were lower than the prespecified margins of non-inferiority; therefore, we reject the null hypothesis and conclude that waterbirth is non-inferior to giving birth out of water.

Rates of the individual components of the neonatal primary outcome were: intrapartum or neonatal death – occurred in three babies born in water (0.3 per 1000 births) and in zero babies born out of water. Respiratory support on a NNU was provided to 91 (0.9%) of babies born in water and to 104 (2.0%) of babies born out of water; (aOR 0.44, one-sided 95% CI $-\infty$ to 0.60). Antibiotics were administered within 48 hours of birth to 263 (2.7%) babies born in water and to 224 (4.4%) babies born out of water (aOR, 0.65, $-\infty$ to 0.79).

There was a higher rate of snapped umbilical cords prior to clamping in the infants born in water compared to those born out of water (1.0% $N = 106$ vs. 0.3% $N = 16$, respectively) (aOR 3.89, one-sided 95% CI $-\infty$ to 6.88). In 8.6% ($N = 926$) of waterbirths, the placenta was also delivered in water. Rates of postpartum haemorrhage (≥ 1000 ml) were similar when the placenta was delivered in water or out of water (aOR 0.70 one-sided 95% CI $-\infty$ to 1.18).

The qualitative work found considerable differences between OUs and midwifery units in relation to equipment and resources, staff attitudes and confidence, senior staff support and women's awareness of water immersion and waterbirth. Findings have several implications for practice: increased exposure to care of women during water immersion and waterbirth is vital to improve the confidence of midwives working in OUs; training for obstetricians and neonatologists on the practicalities and outcomes of pool use could increase support for water immersion and waterbirths; and improved access to antenatal information would help increase awareness of the option to use a pool during labour and birth.

Limitations

Limitations of the study included the inability to reliably identify women with medical or obstetric complications recorded in their medical records and the possibility of confounding between groups that were not known or could not be adjusted for – including reason for getting out of pool.

Conclusions

The POOL Study established that among nulliparous and parous women, without antenatal complicating conditions, who used water immersion during labour, and who did not receive additional monitoring or interventions prior to birth, remaining in the water to give birth was not associated with an increase in the incidence of OASI, or the primary adverse neonatal outcome.

Current NHS midwifery practice relating to labour and birth in water is safe for women and their babies. Women, parents, families, practitioners and policy-makers should be reassured that birth in water, in the context of NHS care, is not associated with increased risks for mothers or their babies. Women considering or using water immersion during an uncomplicated labour should be informed that remaining in the water to give birth is not associated with an increased risk to themselves or their baby, and they should be supported to make evidenced-based, individualised decisions on their care.

Research priorities

1. Interventions to reduce rates of OASI during vaginal births.
2. Women's experiences of use of water during labour and birth, including impact on potential short-term and longer-term impacts, for example, maternal–infant attachment, postnatal depression, sense of control and self-efficacy. This work should focus on marginalised and culturally diverse communities.
3. Impact of waterbirth on neonatal physiology and transition to extrauterine environment.
4. Blood loss measurement in water.
5. Midwifery care during waterbirth, including in the event of non-spontaneous birth of the fetal shoulders.
6. Care of babies following cord snapping.
7. Teaching of care of women during water immersion and waterbirth to student midwives and midwives.
8. Evaluation of the cost effectiveness of waterbirth vs. births out of water.

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