

ORCA - Online Research @ Cardiff

This is an Open Access document downloaded from ORCA, Cardiff University's institutional repository:https://orca.cardiff.ac.uk/id/eprint/151616/

This is the author's version of a work that was submitted to / accepted for publication.

Citation for final published version:

Cannings-John, Rebecca, Gale, Christopher, Lugg-Widger, Fiona V., Milton, Rebecca, Robling, Michael and Sanders, Julia 2022. Protocol and statistical analysis plan for the POOL study: establishing the safety of waterbirth for mothers and babies: a cohort study with nested qualitative component. British Medical Journal

Publishers page:

Please note:

Changes made as a result of publishing processes such as copy-editing, formatting and page numbers may not be reflected in this version. For the definitive version of this publication, please refer to the published source. You are advised to consult the publisher's version if you wish to cite this paper.

This version is being made available in accordance with publisher policies. See http://orca.cf.ac.uk/policies.html for usage policies. Copyright and moral rights for publications made available in ORCA are retained by the copyright holders.



Supplementary material

Supplementary table 1. STROBE Statement—Checklist of items that should be included in reports of cohort studies

	Item No	Recommendation	Page
Title and abstract	1	(a) Indicate the study's design with a commonly used term in the title or the abstract	1
		(b) Provide in the abstract an informative and balanced summary of what was done and what was found	2
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	5
Objectives	3	State specific objectives, including any prespecified hypotheses	5
Methods			
Study design	4	Present key elements of study design early in the paper	5
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	7
Participants	6	(a) Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up	8
		(b) For matched studies, give matching criteria and number of exposed and unexposed	Na
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	9-12
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	8- 10,14/15
Bias	9	Describe any efforts to address potential sources of bias	17/18
Study size	10	Explain how the study size was arrived at	6/7
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	8- 10,14/15
Statistical methods	12	(a) Describe all statistical methods, including those used to control for confounding	13-16
		(b) Describe any methods used to examine subgroups and interactions	16
		(c) Explain how missing data were addressed	17
		(d) If applicable, explain how loss to follow-up was addressed	Na
		(\underline{e}) Describe any sensitivity analyses	16/17

Participants 13*		(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed	
		(b) Give reasons for non-participation at each stage	NA
		(c) Consider use of a flow diagram	NA
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	NA
		(b) Indicate number of participants with missing data for each variable of interest	NA
		(c) Summarise follow-up time (eg, average and total amount)	NA
Outcome data	15*	Report numbers of outcome events or summary measures over time	NA
Main results	16	(a) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	NA
		(b) Report category boundaries when continuous variables were categorized	NA
		(c) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	NA
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	NA
Discussion			
Key results	18	Summarise key results with reference to study objectives	NA
Limitations	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnit of any potential bias		NA
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	NA
Generalisability	21	Discuss the generalisability (external validity) of the study results	NA
Other information			
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	19

^{*}Give information separately for exposed and unexposed groups.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at http://www.plosmedicine.org/, Annals of Internal Medicine at http://www.annals.org/, and Epidemiology at http://www.epidem.com/). Information on the STROBE Initiative is available at http://www.strobe-statement.org.

NICE Intrapartum Care Guidelines

Table 1 and 2 show extracts from NICE Guidance² providing medical conditions or situations in which there is increased risk for the woman or baby during or shortly after labour, where care in an obstetric unit would be expected to reduce this risk. The factors listed in appendix table 3 and 4 are not reasons in themselves for advising birth within an obstetric unit, but indicate that further consideration of birth setting may be required.

Supplementary table 2. Medical conditions indicating increased risk suggesting planned birth at an obstetric unit

Disease area	Medical condition
Cardiovascular	Confirmed cardiac disease
	Hypertensive disorders
Respiratory	Asthma requiring an increase in treatment or hospital treatment
	Cystic fibrosis
Haematological	Haemoglobinopathies – sickle-cell disease, beta-thalassaemia major
	History of thromboembolic disorders
	• Immune thrombocytopenia purpura or other platelet disorder or platelet count below 100×10 ⁹ /litre
	Von Willebrand's disease
	Bleeding disorder in the woman or unborn baby
	Atypical antibodies which carry a risk of haemolytic disease of the newborn
Endocrine	Hyperthyroidism
	• Diabetes
Infective	Risk factors associated with group B streptococcus whereby antibiotics in
	labour would be recommended
	Hepatitis B/C with abnormal liver function tests
	Carrier of/infected with HIV
	Toxoplasmosis – women receiving treatment
	• Current active infection of chicken pox/rubella/genital herpes in the woman or
	baby
	Tuberculosis under treatment
Immune	Systemic lupus erythematosus
	Scleroderma
Renal	Abnormal renal function
	Renal disease requiring supervision by a renal specialist
Neurological	• Epilepsy
	Myasthenia gravis
	Previous cerebrovascular accident
Gastrointestinal	Liver disease associated with current abnormal liver function tests
Psychiatric	Psychiatric disorder requiring current inpatient care

Supplementary table 3. Other factors indicating increased risk suggesting planned birth at an obstetric unit

Factor	Additional information
Previous complications	Unexplained stillbirth/neonatal death or previous death related to
	intrapartum difficulty
	Previous baby with neonatal encephalopathy
	Pre-eclampsia requiring preterm birth
	Placental abruption with adverse outcome
	Eclampsia
	Uterine rupture
	Primary postpartum haemorrhage requiring additional treatment or blood transfusion
	Retained placenta requiring manual removal in theatre
	Caesarean section
	Shoulder dystocia
Current pregnancy	Multiple birth
	Placenta praevia
	Pre-eclampsia or pregnancy-induced hypertension
	Preterm labour or preterm prelabour rupture of membranes
	Placental abruption
	Anaemia – haemoglobin less than 85 g/litre at onset of labour
	Confirmed intrauterine death
	Induction of labour
	Substance misuse
	Alcohol dependency requiring assessment or treatment
	Onset of gestational diabetes
	Malpresentation – breech or transverse lie
	BMI at booking of greater than 35 kg/m2
	Recurrent antepartum haemorrhage
	Small for gestational age in this pregnancy (less than fifth centile or
	reduced growth velocity on ultrasound)
	Abnormal fetal heart rate/doppler studies
	Ultrasound diagnosis of oligo-/polyhydramnios
	• Cholestasis*
	• Labour outside of 37+0 and 41+6*
Previous gynaecological	Myomectomy
history	Hysterotomy

^{*}Some additional conditions, not included in the NICE guidelines, have been identified that if present would be also regarded as contraindications to pool use in labour and therefore if present would classify the woman as 'high risk'

Supplementary table 4. Medical conditions indicating individual assessment when planning place of birth

Disease area	Medical condition			
Cardiovascular	Cardiac disease without intrapartum implications			
Haematological	Atypical antibodies not putting the baby at risk of haemolytic disease			
	Sickle-cell trait			
	Thalassaemia trait			
	• Anaemia – haemoglobin 85–105 g/litre at onset of labour			
Infective	Hepatitis B/C with normal liver function tests			
Immune	Non-specific connective tissue disorders			
Endocrine	Unstable hypothyroidism such that a change in treatment is required			
Skeletal/neurological	Spinal abnormalities			
	Previous fractured pelvis			
	Neurological deficits			

Supplementary table 5. Other factors indicating individual assessment when planning place of birth

Factor	Additional information
Previous complications	Stillbirth/neonatal death with a known non-recurrent cause
	Pre-eclampsia developing at term
	Placental abruption with good outcome
	History of previous baby more than 4.5 kg
	Extensive vaginal, cervical, or third- or fourth-degree perineal trauma
	Previous term baby with jaundice requiring exchange transfusion
Current pregnancy	Antepartum bleeding of unknown origin (single episode after 24 weeks of gestation)
	BMI at booking of 30–35 kg/m2
	Blood pressure of 140 mmHg systolic or 90 mmHg diastolic or
	more on 2 occasions
	Clinical or ultrasound suspicion of macrosomia
	Para 4 or more
	Recreational drug use
	Under current outpatient psychiatric care
	Age over 35 at booking
Fetal indications	Fetal abnormality
Previous gynaecological	Major gynaecological surgery
history	Cone biopsy or large loop excision of the transformation zone
	Fibroids

Supplementary table 6. Wellbeing software fields for primary and secondary outcomes

Outcome	Data source (E3/NNRD) R=retro P=prosp	E3/NNRD Field name	Population
Maternal outcomes			
Primary outcome			
Obstetric Anal Sphincter Injuries (OASI)	E3R/P	AnalgesiaPerineum PerinealRepair PerineumVaginalTears ConsentSuturing	All women
Secondary outcomes			
Intrapartum			
Shoulder dystocia	E3R/P	EpisiotomyReason ShoulderDystocia ShoulderDystociaHelp HeadDeliveredMode	All women
Required management of shoulder dystocia	E3R/P	In babies with shoulder dystocia: McRoberts ManoeuvresPerformed SuprapubicPressure EpisiotomyPerformed PosteriorArm WoodScrewManoeuvre AllFoursPosition OtherManoeuvres	In babies with sh. dystocia
Time from Head born to time of birth (the longer duration the worst outcome)	E3R/P	To be derived by E3: HeadDeliveriedToBirthDuration	All women
Management of the third stage of labour	E3 P E3 R/P	POOLThirdStageMgt/POOLPlacentaDelivered/ Intended PlacentadeliveredHow OxytocinDrug3rd Stage Analgesia3rdStage	All women with a pool birth
Need and reason for obstetric involvement in woman's care including sepsis	E3 P E3R/P	At labour: POOLObstetricCare Postnatally:	All women that used a pool

Outcome	Data source (E3/NNRD) R=retro P=prosp	E3/NNRD Field name	Population
		AnalgeisaPerineum AnaesProcedurePerformed AnaesthsiaAtCaesarean AnalgesiaDelivery DrugsPostDelivery IVTherapyPostDelivery LabourAugmented MLUTransferredOut MLUTransferReason MonitoringChangedInLabour PerineumVaginalTears PlaceOfBirth PlacentaDeliveredHow (MROP) PNT_OtherProbs POOLObstetricCare PostnatalProblems ProblemsIntrapartum ProblemsMaternal ProblemsPostDelivery ReasonForChangeAN ReasondelPlaceChange Transferred Transferred TransferHospital (variables to pick up sepsis) PostnatalProblems Problemspostdelivery problemspostdelivery problemsintrapartum	All women
Maternal position during vaginal birth	E3R/P	DeliveryPosition Semi-recumbent Left lateral Squatting Kneeling	All women

E3R/P	All fours Lithotomy Other Birthing stool Standing	
F2D (D	Other Birthing stool	
E2D /D	Birthing stool	
E2D /D		
F2D /D	Standing	
E2D/D	Standing	
E3R/P	BloodLossAtDelivery +BloodLossAfterDelivery	
		All women
	ProblemsPostDelivery	
	3rd stage drugs:	
	PlacentadeliveredHow	
	OxytocinDrug3rd Stage	
	MOHBloodProductsInfused	
E3R/P		All women
	· -	
	E3R/P	AnaesCriticalIncidents(>1L) ProblemsPostDelivery 3rd stage drugs: PlacentadeliveredHow OxytocinDrug3rd Stage IVTherapyPostDelivery 3rdstage fluids: BloodTransfusion MOHcause MOHManagement MOHOperativeIntervention MOHBloodProductsInfused PNT_BloodTransfusion

Outcome	Data source (E3/NNRD) R=retro P=prosp	E3/NNRD Field name	Population
Postnatal			
Duration of postnatal stay	E3R/P	PN_StayDuration	All women
Breast feeding initiation and continuation (at community discharge)	E3R/P	Fed1hour PNT_Feeding Method FeedingMethodDelivery BNT_FeedingMethod BNT_FeedingType BNT_Breastmilk48Hrs BreastFeedingAt10Days	All women
		FDFeeding (final discharge)	
Higher level care (NB many delivery suites provide a HDU care so may not say)	E3R/P	Postnatal problems Transferred (ITU/HDU/other->main recovery) PNT_Mode PNT_DischargeMethod AnaesCriticalIncidents	All women
Maternal readmission to hospital within seven days of birth	E3R/P	ReAdmission PNT_Reason PNT RoutineCare	All women
Infant Outcomes		_	
Primary outcome			
Composite of 'adverse infant outcomes or treatment' to include:			
any neonatal unit admission requiring respiratory support	E3R/P NNRD	TransferToNN4B/BNT_Separation/ BNT_ReasonNICUAdmission/ BNT_LengthNICUAdmission/ BNT_Destination TimeBirthToResps Respsupportgiven/numberofrespdays/ Methods1-14	All babies
	E3 P	POOLAntibioticCommenced	All babies whose
b) intravenous antibiotic administration within 48 hours of birth (with or without culture proven infection)	NNRD	POOLAntibioticCommenced POOLAntibioticDuration anti48given	mother had a pool birth
c) intrapartum stillbirth or infant death prior to neonatal unit/postnatal ward discharge	E3 NNRD	Outcome/ PbRComplications/ StillbirthClassification Death	All babies

Outcome	Data source (E3/NNRD) R=retro P=prosp	E3/NNRD Field name	Population
Secondary outcomes			
Timing of cord clamping	E3R/P	CordClamping	All babies
	NNRD	CordClamp TimeOfCordClamp	
Apgar scores	E3R/P/	Apgar1MinuteNN4B_Value	All babies
		Apgar5Minutes_Value	
	NNRD	Apgar_1min	
		Apgar_5min	
Incidence of:			
NNU admissions requiring respiratory support		numberofadmissions	
		Respsupportgiven	
Administration and duration of intravenous antibiotics	E3 P	POOLAntibioticsCommenced	All babies
		POOLAntibioticsDuration	
	NNRD	antiGivenIV/numberofantidays	
Cause of intrapartum stillbirth or all deaths prior to neonatal	E3R/P	Outcome (live-/stillbirth/early neonatal death)	All babies
unit/postnatal ward discharge, neonatal deaths that occurred within		StillbirthClassification	
seven days of birth on a neonatal unit/postnatal ward	NNRD	CauseofDeath1-3	
Neonatal resuscitation	E3R/P	DrugsotherProcedures (intubation)	All babies
		DurationBirthToIntubation	
		IntermitPosPresVenti	
		DurationO2Intubation	
	NNDR	TimeBirthToResps	
		Methods1-14	
snapped umbilical cord prior to clamping	E3 P	CordSnap	All babies
skin to skin contact at birth	E3 R/P	SkinToSkinContact	All babies
		SkinToSkinDuration	
first breastfeed within first hour	E3 R/P	Fed1Hour	All babies
culture proven infection	E3 P	POOLBloodCulture	All babies given
	NNRD	POOLCRPResult AnyGrowth	antibiotics
brachial plexus injury	E3 R/P	BirthInjurySuspected	All babies
oracınar piexus injury	NNRD	brachialplexus_injury	All bables
treatment for jaundice	E3 R/P	BNT JaundiceTreatment	All babies
treatment for jaundice	E3 K/P	BNT_JaundiceTreatment BNT_Admitreason	All bables
		DIVI_AUIIIITE ason	

Outcome	Data source (E3/NNRD) R=retro P=prosp	E3/NNRD Field name	Population
		BNT_ProblemsPriorDischarge	
	NNRD	JaundiceTreatmentGiven	
readmission to hospital within seven days of birth	E3 R/P	BNT_Admitreason	All babies
		BNT_ActionTaken	
	NNRD	readmission	
Therapeutic hypothermia	NNRD	thGiven	All babies
Neonatal unit admissions	NNRD	numberofadmissions	All babies
Respiratory support (same as primary)	NNRD	Respsupportgiven	All babies
Confirmed neonatal sepsis			
Highest CRP results	E3 P	POOLCRPResult	All babies given antibiotics
Successful / attempted lumbar puncture	E3 P	POOLBabyLumbarPunc	All babies given antibiotics
Blood culture positive with a recognised pathogen (excluding skin commensal organisms)	E3 P	POOLBloodCulture	All babies given antibiotics
	NNRD		
Delivery of placenta in or out of water	E3 P	POOLPlacentaDelivered	All women with a pool
		PlacentaDeliveredHow	birth
Third stage management	E3 R/P		