Neonatal Resuscitation Online Registry in Shenzhen: protocol for a prospective, multicentre, open, observational cohort study

Supplementary File 1

Standard Protocol Items for Observational Studies (SPIROS)

Table 1: Checklist of preliminary items

Section and topic	Description / sub-categories	Addressed on page number
i) General Information		
Title	Descriptive title identifying study design	page 1
Protocol version	Version or amendment number and date and summary of changes	Text headers
Protocol summary	Brief summary of protocol research	pages 3-4
Sponsor and partner institute name	Name of sponsor and participating institutes (if applicable)	NA
Investigators name	Name of principal and co investigators	pages 1-2
Affiliation of investigators	Affiliated institutions of investigators	pages 1-2 and 25
Principal researcher contact detail	Name, email address, affiliation of Principal researcher for correspondence.	pages 1-2
Table of content	Table of content	Table 1 and Table 2
Page number	Page number on each page of protocol	Pages 5-20
List of Abbreviations	A detailed List of all abbreviations used in protocol with full form.	NA
ii) Introduction		
Background of study	Scientific background of study	Pages 5-6
Review of prior research	Summary of all previous relevant research	Pages 5-6
Rationale of study	Justification for conducting the study	Page 6
Aim	Broader aims and specific objectives of the study	Page 7
Objective of study	Primary and secondry objectives of study	Page 7
Prespecified hypothesis	Prespecified null or alternative hypothesis	NA

Neonatal Resuscitation Online Registry in Shenzhen: protocol for a prospective, multicentre, open, observational cohort study

Supplementary File 1

iii) Methods		
Study design	Description of type/design of study	Page 7
Study setting	Description of setting, locations, relevant dates, including periods of recruitment/survey, exposure, follow-up, and data collection. Schedule of study procedure – Figure or table	Pages 7-16 supplementary file 2
Sample size	Estimated number, calculation and assumptions Power calculation	Pages 17-18 Pages 17-18
Sampling procedure	Description of sampling strategy to ensure representativeness and control of potential bias	Pages 12-13 and 16-17
Participants	**Cohort study**—eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up. For matched studies, give matching criteria and number of exposed and unexposed **Case-control study**—Give the eligibility criteria, and the sources and methods of case ascertainment and control selection. Give the rationale for the choice of cases and controls For matched studies, give matching criteria and the number of controls per case **Cross-sectional study**—Give the eligibility criteria, and the sources and methods of selection of participants	Pages 9 and 12-13 NA
Variables	● All outcomes ● Exposures- definition of exposure of interest ● Predictors ● Potential confounders	Pages 13 -16

Neonatal Resuscitation Online Registry in Shenzhen: protocol for a prospective, multicentre, open, observational cohort study

Supplementary File 1

	● Effect modifiers	
Data Sources/Measurement	● 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 ● Data collection points table ● Blinding procedure	Pages 12-17 NA Table 2 NA
Bias	Describe any efforts to address potential sources of bias More specifically- ● Information bias ● Selection Bias ● Control for confounding	Pages 12-13 and 16-17
Statistical analysis plan	● Method of primary / secondary outcomes and additional analysis ● Handling of missing data ● Post-hoc analysis	Page 18 NA NA
Handling of withdrawals and lost to follow up	Describe the procedures to be followed when a participant ceases participation in the study prematurely or is lost to follow up	Page 17
Replacements	Provide information on whether or not participants who discontinue the study will be replaced via additional recruitment to maintain the required sample size.	Page 17
Outcome	Define and describe all primary and secondary outcome or lost to follow up	Pages 16
Database management	Detail plan of database management including: ● Data collection (electronic or paper based)	 Pages 12-16

Neonatal Resuscitation Online Registry in Shenzhen: protocol for a prospective, multicentre, open, observational cohort study

Supplementary File 1

	● Source data ● Data entry ● Data editing ● Coding ● Data storage ● Record retention ● Data confidentiality	Pages 12-16 Page 12-13 Page 12-13 Page 12-13 Page 12-13 Page 12-13 Page 17
Validation of instrument	Reliability / validity of instrument or plan to establish validation	Pages 12-13 and 16-17
Follow up	Plan of follow up and addressing lost to follow up	Page 12-13
Quality control	Method of quality control Monitoring (internal and external) Training of surveyors	Pages 16-17 Pages 16-17 Page 7, 12-13 and 16-17
Quality assurance	Plan of quality assurance	Pages 16-17
Expected outcome /results	A brief description of expected outcome or results	Pages 3-4 and 19
iv) Ethical consideration		
Ethical approval	Weather it has been obtained and name of ethical committees. If approval not sought, Reason	Pages 4 and 20
Agreement and consent	Method of taking consent. Reason if consent not sought	Page 9
Risk / Harm to participants	Any potential risk or harm to study participants	NA
Adverse event and Severe adverse event reporting	Outline how Adverse Event and Severe adverse event information will be collected.	NA
v) Reporting and dissemination		

Neonatal Resuscitation Online Registry in Shenzhen: protocol for a prospective, multicentre, open, observational cohort study

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Protocol amendments	Methods of communicating to investigators/ IRBs and documenting	Pages 16-17
Dissemination	How results will be disseminated to participants, practitioners, public	Pages 8 and 20
Publication Plan	Who has right to publish; restrictions; authorship guidelines Open Access	Pages 17 and 20 Page 26
Reporting of early stopping	Dissemination of results if trial is stopped early (for any reason)	NA
vi) Others		
Limitations	Limitations of proposed study, including risk of bias	Page 4
Strength of study	Highlight strengths of proposed study	Page 4
References	List of references cited in protocol	Pages 20-24
Data collection forms	Summary table of all forms used for data collection at each point of study	Table 2
Informed consent forms	Sample of informed consent form, translated into local language	supplementary file 5
Funding	Source of funding and the role of the funders for the present study	Page 25
Acknowledgement for protocol development	Acknowledgement of persons involved in protocol preparation	Page 25
Data sharing policy	To describe how data will be made available in public domain.	Page 20
Contributions of authors to protocol	Listed authors should have participated sufficiently in prepartion of protocol with details of their contribution.	Page 25
Trial registry	For observational studies also registered as trial	Page 4
Annexures	Data collection form /instruments Informed consent form Standard operating procedures (SOPs) Detailed Statistical analysis plan (SAP)	supplementary file 3 supplementary file 5 supplementary file 2 Page 18