Paediatric Clinical Research Infrastructure Network

Procedures for the setup of neonatal trials

Neonatal trials and data collection by age groups: Points to consider

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Description	This tool provides a checklist of age-related data to be collected for neonatal studies
Key words	Neonatal trial, Protocol development, Guidance document, Tool, Age groups, Data collection

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Disclaimer: **Sponsors and researchers unfamiliar with clinical trials in neonates and/or neonatology are advised to seek expert advice due the complexity of neonatology.**

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Introduction

In neonatal clinical trials age reflects changes in pharmacokinetics and pharmacodynamics and factors modifying efficacy and safety.[1-3] For example a neonate born at 24 weeks gestation does not have the same metabolic capacities as one born at 39 weeks.[2-4] Similarly, developmental maturation and with it, reference values for laboratory parameters and vital signs change rapidly in neonates.[3,5] Data collection and analysis needs to take all these factors into account.

Data collection by age group in neonatal trials: Points to consider

A minimum of data should be collected in all neonatal trials including the following three dates :

- Date of the first day of last menstrual period or estimated date of delivery based on foetal ultrasound
- Date of birth
- Date and, where appropriate, time (hour and minutes) at study time points (e.g. administration of a study drug, investigations, developmental assessment)

It is recommended to enter exact dates in order to capture age in days, because this will allow the correct calculation of postmenstrual and corrected age in weeks and days (Table 1).

Conclusions

In conclusion, in neonatal clinical trials age is a proxy for maturity and of covariates influencing morbidity and mortality. It is therefore important to exact dates are captured for data points relating to neonatal age and the protocol should clearly state how gestational age is determined. This will facilitate stratified data analysis by age group. Existing standard age categories should be used to facilitate comparison with published data and future meta-analyses. However, additional age groups may be considered based on the study population and trial objectives.

Competing interests

All authors consider not having any competing interests for this tool. BA has worked for GlaxoSmithKline between October 2006 and September 2009 and holds company shares. Between October 2009 and May 2015 she has worked for Novartis.

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Table 1. PedCRIN Tool - Data collection in neonatal trials: Check list*

Data items	Included in the protocol/ Case Report From (CRF)	
Date of first day of last menstrual period		
	Yes	
	No	
	Not applicable	
Date of birth		
	Yes	
	No	
	Not applicable	
Date at study time points		
Date at inclusion	Yes	
	No	
	Not applicable	
Date of start of study drug treatment	Yes	
	No	
	Not applicable	
Date of completion of study drug treatment	Yes	
	No	
	Not applicable	
Date of pharmacokinetic sampling	Yes	
	No	
	Not applicable	
Date at occurrence of adverse events	Yes	
	No	
	Not applicable	
Date of outcome assessment	Yes	
	No	
	Not applicable	
Date of end of follow-up assessment	Yes	
	No	
	Not applicable	
Date of discharge/transfer from hospital	Yes	
	No	
	Not applicable	

* Not exhaustive

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