Children's Oxygen Administration Strategies Trial - Nutrition: COAST-Nutrition

Data Management Plan
Version 1.0

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1 Version history

Version number	Author initials	Issue date	Reason for change	Superseded documents
1.0	KT			

2 Study milestones

Activity	Date
First approved protocol	
Latest approved protocol	
Dataset completed and signed-off	
First approved CRF	
Latest approved CRF	
Database completion & sign off	
First patient recruited	

3 Purpose

COAST-Nutrition is a randomised controlled trial with a target sample size of 840 individuals. The study aims establish whether supplementary feeding for 56-days (8 weeks) using Ready to Use Therapeutic Feeds (RUTF) in all children versus usual standard care will improve outcome at 90-days

4 Dataset

The target population is patients admitted to participating hospitals with suspected severe pneumonia. Patients are screened for eligibility at admission, and once consent has been obtained from eligible patients, baseline personal and medical information (inclusion & exclusion criteria, clinical variables from a physical examination, list of samples taken & tests done, clinical history & treatment and clinical examination for this illness, working diagnosis) are collected.

At 48 hours following admission, surviving patients will be randomised and data collected on baseline anthropometric measurements. Data collected at admissions for consenting patients who were not subsequently randomised at 48 hours will be retained in order to describe and compare the characteristics of the randomised and non-randomised groups.

Following randomisation, data is collected at hospital discharge (survival status, final diagnosis, and details of nutritional treatment prescribed), and at 28, 90 and 180 days post randomisation (including anthropometric measurements neurodevelopmental assessment, and compliance with randomised treatment).

Only data which are necessary to achieve the stated objectives of the study will be collected. The data which will be collected can be found in the Case Report Form (CRF) v2.0 dated 5th September 2018.

5 Web portal

Data will be recorded during clinical assessments and extracted from patient medical records. The study site coordinator will transcribe data from the relevant source document to the case record forms (CRF). Following 100% source document verification of the CRF by the trial monitor (as was the case in the FEAST trial) data will be entered at each site by the data management team onto OpenClinica, a web-based, open source, FDA approved, clinical data management system from which data queries can be raised, clinical summaries requested for endpoint review. Security is enforced through authentication of users by use of encrypted passwords. Different access level accounts authorize users on actions they may perform on the database. The site will retain the original paper CRFs. Data will be checked centrally by KCTF and undergo validation checks for completeness, accuracy and consistency of data. Data queries that arise from these checks will be sent from KCTF to the trial site coordinators. The trial site coordinator is required to ensure that queries are resolved as soon as possible, including updating the relevant paper CRFs and the trial database as required. The KCTF will send reminders for any overdue data or outstanding queries. Ongoing data entry and validation and adherence to the trial protocol at sites will be closely monitored by KCTF; any concerns will be raised with the site PI.

An audit log will keep track of all changes made to the database. The system will be maintained and hosted by the Kilifi Clinical Trials Facility (KCTF) at the Kenya Medical Research Institute (KEMRI).

Methods for data collection and data entry will be documented in trial Standard Operating Procedures (SOPs). Technical details of variables and their coding will be recorded in a detailed Dataset Specification.

6 Monitoring plan

Each participating site will have a Site Initiation Meeting prior to opening recruitment.

Each participating site will receive at least one monitoring visit during the recruitment period.

Monitoring will start with 100% source document verification, then will be reviewed for each site once a satisfactory and sustained performance in quality assurance is established. All monitoring will adhere to the ICH-GCP guidelines (E6(R1), 1996).

A detailed site initiation visit (SIV) will be performed at each site by staff from KCTF. The SIV will include training in the trial procedures, such as delivering the trial treatments, reporting guidelines for AEs and data collection and management. All staff at sites involved in the trial will receive formal training in GCP through a dedicated training programme during the SIV and through an on-line course.

Local monitoring teams, responsible to KCTF, will oversee the standards and quality of the trial at each site. All monitors will be appropriately qualified and trained.

At each monitoring visit, monitors will:

- verify completeness of Investigator Site File;
- assess for any non-adherence to protocol;
- review eligibility verification and consent procedures;
- look for missed AE recording/reporting;
- verify completeness, consistency and accuracy of data being entered on CRFs; and
- provide additional training as needed.

The monitors will require access to all patient medical records including, but not limited to, laboratory test results and prescriptions. The PI or delegated local investigator should work with the monitor to ensure that any problems detected are resolved.

7 Screening and recruitment

Potentially eligible patients will be screened against the inclusion and exclusion criteria by local research teams. Patients who are eligible and randomised, eligible and not randomised or who meet the inclusion criteria but one or more of the exclusion criteria will be recorded on the screening and enrolment log.

8 Adherence and Data Quality

Data will be validated on data entry through the Rules function of OpenClinica, according to validation rules pre-specified as part of the Dataset Specification. Source data verification will be undertaken during on-site monitoring visits. Further data validation to identify illogical or inconsistent data (including potential duplicate records) will be undertaken using standardised routines on receipt at ICNARC CTU. Queries arising from this validation process with be discussed with the trial team at KCTF and any corrections required will made in the OpenClinica portal (with appropriate documentation to the source CRF).

Treatment of withdrawals and definition and identification of non-adherence is fully specified in the Statistical Analysis Plan (SAP).

9 Final data lock

Data will be remotely extracted by ICNARC CTU following validation, and stored in their original csv format in a restricted folder accessible only to the CTU statistics team, hosted on a secure server according to standard ICNARC CTU data security policies.

In accordance with ICNARC CTU policy, research data will be archived for 10 years following the end of the study.

10 Data sharing and access

Summary trial information (metadata) will be provided via the study website and the MRC Gateway. The COAST Data Sharing Policy, including the criteria by which sharing/access requests are assessed and the processes and timeframe by which the requests are assessed, will be published on the study website.

The ownership of the COAST-Nutrition dataset will lie with the COAST Trial Steering Committee, who will approve all requests for use of trial data before and after the trial ends (also to be approved by the COAST Data Monitoring Committee). The dataset will be held electronically for at least 20 years after the end of the trial in accordance with our local and MRC policies. Independent oversight of the data access process will be provided by the ICNARC Board of Trustees.

Study data will be retained for exclusive use for primary research by the study team until submission of the final primary research publication as documented in the COAST Dissemination Plan, to be signed-off by the Trial Steering Committee during the course of the study (anticipated to be within one year of the final patient follow-up).

All trial data will be anonymised prior to sharing. Consent procedures will include provision for sharing of anonymised data. As part of the consent process, proposed procedures for

data sharing will be set out clearly and current and potential future risks associated with this explained to research participants.

External users will be bound by a Data Sharing Agreement, which will be issued and signed by appropriate authorities before data are released or analyses are performed on behalf of the requester. Data Sharing Agreements will prohibit any attempt to (a) identify study participants from the released data or otherwise breach confidentiality, (b) make unapproved contact with study participants.