Childhood Acute Illness & Nutrition Network

KEMRI | Wellcome Trust Clinical Trials

Pancreatic Enzymes and Bile Acids: A Non-Antibiotic approach to Treat Intestinal Dysbiosis in Acutely Ill Severely Malnourished Children

Study Specific Procedure	**SSP No:** CL02 **Version No:** 1.0 **Supersedes:** None **Effective Date:** 18th October 2021

Title: Enrolment Procedure

	NAME	**SIGNATURE**	**DATE**
PREPARER	Johnstone Thitiri		**15th June 2021**
Q.A. AUTHORITY	Aisha Bwika		**16th October 2021**
APPROVING AUTHORITY	Robert Bandsma		**17th October 2021**

1.0 PURPOSE / INTRODUCTION:

- PB SAM is a trial of pancreatic enzymes and bile salts aimed at improving outcomes of acutely ill children admitted to hospitals with severe acute malnutrition. The investigational products are introduced during admission as an intervention in additional to WHO standards and guidelines for care of children with severe malnutrition. The intervention lasts for a duration of 21 days.
- Enrolment is considered valid upon assignment of trial drugs and after the first doses have been provided, a process that must be promptly done as close to the time of admission as possible, but not later than 72 hours from the time a child has been admitted in the ward.
- This SOP describes the procedures to be undertaken by staff in order to complete enrolment of eligible and consented participants to join the PB-SAM trial in accordance with the approved protocol.

2.0 SCOPE / RESPONSIBILITY:

- This SOP applies to study clinicians, nurses and fieldworkers involved in enrolment of study participants.
- The Principal Investigator, through the site investigators retains the overall responsibility on implementation of these standards and recruitment of correct population of participants according to approved protocol.

3.0 DEFINITIONS /ABBREVIATIONS:

3.1 **CRF:** Case Report Form

3.2 **SOP:** Standard Operating Procedure

3.3 **ICH GCP:** International Conference on Harmonization / Good Clinical Practice standards

3.4 **SAM:** Severe Acute Malnutrition

3.5 **OPD:** Out-Patient Department

3.6 **WHO:** World Health Organization

4.0 MATERIALS

4.1 Screening log

4.2 Screening form

4.3 CRF

4.4 Signed ICFs

5.0 METHODOLOGY:

5.1 General consideration

- Study teams at the hospital sites should exercise due diligence to ensure that ONLY eligible participants and who have given informed consent are enrolled.
- Enrolment procedures will happen at the points of admission or in the Paediatric wards depending on site characteristics for flow and admission of patients.
- To enroll a participant into the PB-study, the child must have been screened for eligibility (see Screening SOP) and given informed consent (See Informed Consent SOP).

5.2 Enrolment process:

5.2.1 Make a MANDATORY final check of eligibility by reviewing the screening form again.

5.2.2 Confirm a duly signed informed consent form is present and review completeness and accuracy before enrolling. Any unsigned or incomplete sections must be corrected here before proceeding with enrolment.

5.2.3 Aim to enroll participants as close to the time of admission as possible. However, enrolment can occur up to 72 hours after admission in the ward.

5.2.4 Ensure presence of the following documents;

a) Pre-printed study number allocation log,

b) Enrolment envelope,

c) Enrolment log

d) Pre-printed CRF folder

See snapshot below of a study number allocation log:

	PB SAM TRIAL			
Trial number allocation log				
Trial number *(Cross out)*	DATE OF ENROLMENT	PARTICIPANT INITIALS	STAFF INITIALS	REMARKS
01/01/001				
01/01/002				
01/01/003				
01/01/004				
01/01/005				
01/01/006				
01/01/007				
01/01/008				

5.2.5 Check from the Trial number allocation log to identify the next chronological number due for allocation.

5.2.6 Each study site will be provided with sealed envelopes, labelled externally with study IDs. The sealed enveloped will contain the following;

5.2.6.1 A card with printed study ID same to the ID on the envelope.

5.2.6.2 Free printed stickers of study ID to be placed as follows; 1 for CRF, 2 to be placed onto each the investigational product box, 1 for follow up card, and extra for ICF, Lab request forms.

5.2.6.3 Follow up card

5.2.7 Pick the next available envelope according to the trial number allocation log above ensuring a perfect match of the number

Figure 1:Adopted from WikiHow

5.2.8 With the allocated number at hand, retrieve the investigational products (2 boxes of Ursodeoxycholic acid or Placebo and Creon or Placebo). This will complete the enrolment package

5.2.8.1 Completed Study ID allocation log

5.2.8.2 Sealed envelope bearing same study ID as ID allocated on the log

5.2.8.3 A pre-printed CRF folder

5.2.8.4 2 boxes of investigational product bearing same ID as in 4.2.7.2 above

5.2.8.5 Enrolment log

5.2.9 **Open the envelop. This now means the participant is ENROLLED and is in the trial.**

5.2.10 Confirm the study ID on the envelope matches the ID on the card inside. The free stickers inside must also bear same Study ID. Confirm a blank follow up card is in enclosed in the envelope.

5.2.11 Take one sticker and fix on the front page of the CRF. Confirm the pre-printed CRF number matches the new affixed sticker ID.

Fix the remaining stickers as follows;

- 2 to the Ips
- 1 ICF
- 1 follow up card

- Lab request form

5.2.12 Go to participant bedside or other section in the ward to complete enrolment process and collect relevant information related to the trial.

5.2.13 Ensure presence of other documents such as screening log, informed consent document and medical file for use in CRF completion.

5.2.14 First start by completing confirmation of eligibility on the first section of CRF as well as confirmation of informed consent data.

5.2.15 Review the participant's hospital file or if allowed clerk the participant and use the information to complete enrolment CRF.

5.2.16 Next, collect research samples. Aim for this to be collected alongside routine admission blood samples. Collect the rectal swab first because the procedure is the less distressing to the patient than blood sample collection. Collect stool at any time from here whenever the child gets the next bowel movement. Refer to sample collection SOPs for Blood, rectal swabs, and stool RESPECTIVELY.

5.2.17 Once all information and research samples have been collected, finish the enrolment process by administering the FIRST DOSES of the investigation products (Refer to Drug administration SOP).

5.2.18 Now complete the enrolment log with enrolment details. Example below

DATE OF ENROLMENT dd/mm/yyyy	SCREENING No.	SUBJECT INITIALS	STUDY ID	REMARKS	STAFF INITIALS

5.2.19 Ensure there is minimum time spent from data collection to administering of the first dose aimed at a maximum of 2 hours from initiation of enrolment.

6.0 APPENDICES:

6.1 Trial number allocation log

PB SAM TRIAL
Trial number
allocation log

Trial number (Cross out)	DATE OF ENROLMENT	PARTICIPANT INITIALS	STAFF INITIALS	REMARKS
PB 30001	23 Oct 2021	AMT	INJ	1st participant
PB 30002	24 Oct 2021	KRM	CLW	-
PB 30003	24 Oct 2021	MSL	SAT	Kwash child
PB 30004	26 Oct 2021	BLT	MUC	Under 6 months
PB 30005				
PB 30006				
PB 30007				
PB 30008				
PB 30009				

6.2 Enrolment log

DATE OF ENROLMENT dd/mm/yyyy	SCREENING NO	SUBJECT INITIALS	STUDY ID	REMARKS	STAFF INITIALS

7.0 REFERENCES:

7.1 PB-SAM Protocol

7.2 ICG GHP Guidelines

8.0 DOCUMENT CHANGE HISTORY

Version Table:

Version 1.0: Title: **Enrolment Procedure**	Dated: **18th October 2021**	SSP No.: **CL02**	No. Pages: **8**
Version 2.0: Title:	Dated:	SSP No.:	No. Pages:
Version 3.0: Title:	Dated:	SSP No.:	No. Pages:
This document is effective from the date of training/last approval signature and will be reviewed in two years.			

SSP Review and Updating Logs

DATE	NAME OF REVIEWER	SIGNATURE	REASON FOR REVIEW AND CHANGES MADE

SSP AWARENESS LOG

I, the undersigned below, hereby confirm that I am aware that the accompanying SSP is in existence from the date stated herein and that I shall keep abreast with the current and subsequent SSP versions in fulfillment of Good Clinical Practice (GCP).

Number	Name	Signature	Date (dd/mmm/yyyy)
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