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

Standard Operating Procedure	**SSP No:** CL03 **Version No:** 1.0 **Supersedes:** None **Effective Date:** 19th October 2021

Title: Follow Up Procedure

	NAME	SIGNATURE	DATE
PREPARER	Isaiah Njagi		**15th June 2021**
QUALITY ASSURANCE AUTHORITY	Aisha Bwika		**16th October 2021**
APPROVING AUTHORITY	Robert Bandsma		**17th October2021**

1.0 PURPOSE / INTRODUCTION:

This SOP describes follow up of study participants and the schedule of events in the PB-SAM study.

2.0 SCOPE / RESPONSIBILITY

2.1 This SOP applies to all study clinicians, nurses and field workers involved in the management of study participants.

2.2 The principal investigator through the lead clinician retains the overall responsibility of the implementation of this SOP

3.0 DEFINITIONS

3.1	**CRF:**	Case Report Form
3.2	**PB-SAM**	Pancreatic Enzymes and Bile Acids: A Non-Antibiotic approach to Treat Intestinal Dysbiosis in Acutely Ill Severely Malnourished Children
3.3	**MUAC**	Mid upper arm circumference
3.4	**SOP**	Standard Operating Procedure

4.0 EQUIPMENT / MATERIALS

4.1 Follow up visits record card/book

4.2 Pens

4.3 Mobile phone

4.4 Gloves

4.5 Clean swabs

4.6 CRFs

4.7 Thermometer

4.8 Stadiometer

4.9 Length board

4.10 Weighing scale

4.11 MUAC tapes

4.12 Rectal swabs

4.13 Laboratory request form

5.0 METHODOLOGY:

Introduction and general considerations

5.1 Study participants enrolled into PB-SAM study will be reviewed daily by the study team, working together with the hospital staff to provide the best care available in the hospital.

5.2 The study participants will be followed up for 60 days from the day of enrolment with 2 scheduled follow-up visits: day 21 and day 60. Anthropometry will be recorded at enrolment and on every day during the index admission as well as all the 2 follow up visits. During the follow up visits, rectal swabs/ stool will be collected on day 21 and day 60.

5.3 Blood samples will be collected only on day 21 follow up visit.

5.4 The parent/guardian of the study participant will be informed of the scheduled study visits during consenting. During discharge, the clinician/FW/study nurse will inform the parent/guardian of the next scheduled date of follow up. The date of all follow up visits will also be indicated on the study participant's card/ follow up book.

5.5 The field workers and clinicians will prepare and maintain a follow up visit record/log showing the date when each enrolled study participant is due for their follow up visits. The nurses, clinicians or field workers will make a telephone call at least two days to the scheduled visit to remind the study participant's parent/guardian of the study visit.

5.6 The parent/guardian of each enrolled study participant will be informed to always carry the follow up card/book any time when the child visits the study hospital or any hospital within the 60-day study period.

5.7 During each follow up visit, the field worker/clinician/study nurse will introduce themselves to the parents/guardian/child, check study identification card/book of the subject, confirm their identity and confirm that they are due for a study visit. They will then confirm that the parent/guardian is still interested in their child continuing with the study and inform them of the study activities scheduled for that day. They will then take anthropometric measurements and hand over the child to the clinicians for clinical review/assessment and filling in of the follow up CRF. The study samples will then be collected as per the sampling schedule.

5.8 The field workers/clinicians will make efforts to trace defaulters via phone call and SMS and try to trace those not reachable at their homes before they are declared lost to follow up.

5.9 After the day 60 visit, the clinicians/field workers will inform the parents/guardian that they have completed the study and will not need to come for any other study visit.

6.0 APPENDICES

6.1 Appendix 6.1: Study course, data collection and sample collection schedule for trial participants

	Study Enrolment (≤ 72 hr. hospital admission))	DAILY IN HOSPITAL	DISCHARGE	Day 21	Day 60	READMISSION
Standard case management	X	X	X	X	X	X
Give study information	X	X	X	X	X	X
Screening & eligibility	X					
Enrolment	X					
Informed consent	X					
Anthropometry	X	X	X	X	X	X
Clinical data collection	X	X	X	X	X	X
Blood sample	X			X		X
Rectal swab/stool	X		X	X	X	X
12 hourly capillary blood gas & lactate (days 1-5 only)		X				

7.0 REFERENCES

PB-SAM protocol.

8.0 DOCUMENT CHANGE HISTORY

Version Table:

Original: Title: **Follow Up Procedure**	Dated: **19th October 2021**	SOP No.: **CL03**	No. Pages: **6**
Version: Title:	Dated:	SOP No.:	No. Pages:
Version: Title:	Dated:	SOP No.:	No. Pages:

SOP Review and Updating Logs

DATE	NAME OF REVIEWER	SIGNATURE	REASON FOR REVIEW

SOP AWARENESS LOG

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

Number	Name	Signature	Date (dd/mmm/yyyy)
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