Standard Operating Procedure: Drug Dispensing Procedure

Purpose

To describe the procedure of drug dispensing to eligible study participants and to ensure accurate timing and documentation.

Intended Users

Clinical trial pharmacist, clinical trial staff, study/trial nurse

Responsibility

1. This SOP applies to study nurses who will retain the responsibility of managing and dispensing study drugs.
2. The Principal Investigator through the lead clinician retains the overall responsibility of ensuring correct study drugs are given study participants in a safe and timely way.

Definitions

Kgs - Kilograms
Mgs - Milligrams
Mls - Millilitres
IU - International units

Required Materials

Tray/kidney dish

Assorted syringes

Needles

Clean gloves

Cotton swab

Receivers: for dirt

Methylated spirit in a container with nozzle sprayer

Pancreatic enzyme

Ursodeoxycholic acid/Placebo

Pancreatic enzyme/Placebo

Drug file

Stationery-CRF, treatment sheet, pen, calculator

Procedure

Oral administration of Pancreatic enzyme/Placebo (granules)

- The prescription dose for pancreatic enzyme/placebo recommended during the study will be ranged from 2000 IU/kg/day to 4000 IU/kg/day in two divided doses.
- The medication will be scoops containing granules packaged in bottles.
- The medication will be given in scoops according to the weight bands. A conversion table for translating dose prescribed from IU into scoops of drug to give for each weight band is shown in Appendix 1.
- For oedematous malnutrition participants, weight used for dosing is reduced by a pragmatic 10%.
- The content will be applied into the mouth using a small spoon mixed with food or milk or by nasogastric tube if this is in place for feeding.
- Clean and disinfect tray/kidney dish for use. Wash and dry hands. With an assistant confirm participant name, study number, dose and frequency.
- Together with an assistant, determine the quantity of drug to give in scoops using the pre-calculated dose chart for this formulation of pancreatic enzyme/placebo
- Open the pancreatic enzyme/placebo bottle and draw the correct number of scoops using the specific study drug spoon.
- Add the medication to the meal (food or milk) to be given to the participant and mix.
- Explain the procedure to parent/guardian seeking permission to proceed. Confirm participant identity i.e. name, study number and dose/route prescription. Give the meal (food or milk) containing medication to parent/guardian and let the infant eat/drink. If feeding via NGT, add the medication containing meal through the tube. Remain with the participant until all of the drug is swallowed.
- Evaluate for vomiting or any other reactions up to 2 hours of administration.
- If there is emesis within 30 minutes after administration of the study drug, the complete dose will be repeated.

Documentation:

- Document the dose of the drug given in the patient's treatment sheet and study drug dispensing log for pancreatic enzyme/placebo (Appendix 2). In case of adverse reaction,

a detailed account must be documented in the participant's notes and in the SAE form for SAEs.

Oral administration of Ursodeoxycholic acid/Placebo (liquid)

- The prescription dose for ursodeoxycholic acid/Placebo recommended during the study will be 10 mg/kg twice per day. A conversion table for translating dose prescribed from mg into MLs of drug to give will be made available during the study and is appended as Appendix 3 in this SOP.
- The medication will be given according to weight bands as shown in Appendix 3.
- For oedematous malnutrition participants, consider the weight is pragmatically reduced by 10%.
- Clean and disinfect tray/kidney dish for use. Wash and dry hands. With an assistant confirm participant name, study number, dose and frequency.
- Together with an assistant, determine the quantity of drug to give in mls using the pre-calculated dose chart for ursodeoxycholic acid as shown in appendix 3.
- Shake the ursodeoxycholic/placebo bottle and draw the correct amount using an appropriate size of syringe. Do NOT use needle.
- Explain the procedure to parent/guardian seeking permission to proceed. Confirm participant identity i.e. name, study number and dose/route prescription. Give the syringe to parent/guardian and let the infant suck the medicine out of the syringe or instruct to squeeze the content into the mouth on the inside of the cheeks. If feeding via NGT, push the drug through the tube and flush tube using 5mls of clean drinking water. Remain with the participant until all of the drug is swallowed.
- Evaluate for vomiting or any other reactions up to 2 hours of administration.
- If there is emesis within 30 minutes after administration of the study drug, the complete dose will be repeated.

3. Documentation:

- Document the dose of the drug given in the patient's treatment sheet and study drug dispensing log for oral medication (Appendix 4). In case of adverse reaction, a detailed account must be documented in the participant's notes and in the SAE form for SAEs.

Appendices

Appendix 1: . Dosing range pancreatic enzymes

Weight (Kg) From	Weight (Kg) To	Dose (scoops)	Dose (IU Lipase)	Upper range (IU/kg/dose)	Lower range (IU/kg/dose)
2.50	4.99	2	10000	4000	2000
5.00	7.49	4	20000	4000	2670
7.50	9.99	6	30000	4000	3000
10.0	15.0	8	40000	4000	2667

Appendix 2: Pancreatic enzyme/Placebo Dispensing Log

Drug: Pancreatic enzyme/Placebo
SITE: _____

Date (ddmmyyyy)	**Time (24HR)**	**Study ID**	**Quantity Issued (scoops)**	**Staff initials**

SUMMARY OF QUANTITIES USED:				

Pancreatic enzyme/Placebo		

Appendix 3. Dosing range Ursodeoxycholic acid

Weight (Kg) From	Weight (Kg) To	Dose (ml)	Dose (mg)	Upper range (mg/kg/dose)	Lower range (mg/kg/dose)
2.50	3.99	0.6	30	12.0	7.5
4.00	5.99	1.0	50	12.5	8.3
6.00	7.99	1.4	70	11.7	8.7
8.00	9.99	1.6	90	11.3	9.0
10.0	15.0	2.2	110	11.0	7.3

Appendix 4: Ursodeoxycholic acid/Placebo Dispensing Log

Drug: Ursodeoxycholic acid/Placebo
SITE: _____

Date (ddmmyyyy)	Time (24HR)	Study ID	Quantity Issued (ml)	Staff initials

SUMMARY OF QUANTITIES USED:				
Ursodeoxycholic acid/Placebo				

References

PB-SAM study protocol.

Document History

Version	Author	Approved by	Signed	Dated
1.01 CHAIN PB-SAM Drug accountability SOP	Amber Farooqui	Robert Bandsma		29-01-2021

Site Training Record

All sites are required to maintain a master copy of this SOP that documents the site staff that have been trained on this SOP.

Document History				
Version No.	**Trained staff initials**	**Signature of trained staff**	**Date**	**Trainer's Initials**
1.01	KDT	Example row	1st Jan 2016	DM

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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