ISRCTN11571116 https://doi.org/10.1186/ISRCTN11571116

Stool frequency in Severe Acute Malnutrition

Submission date	Recruitment status	[_] Prospectively registered
29/11/2013	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
15/01/2014	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
19/10/2017	Nutritional, Metabolic, Endocrine	

Plain English summary of protocol

Background and study aims
Many young children in developing countries die because of malnutrition. If the children are admitted to hospital with severe acute malnutrition, the likelihood of dying is higher if they also suffer from diarrhea. It has been noticed that the mothers of many children might not always give an accurate report of the child's stool frequency and consistency. In order to provide good treatment an accurate report is very important. This study will compare what the mothers say about their children's defecation habits to what the healthcare workers are able to observe with the help of diapers. Our aim is to determine whether stool output as assessed by the maternal /carer recall method is same as when assessed using directly observed diapers in children with severe acute malnutrition.

Who can participate?
All children admitted to the Nutritional Rehabilitation Center of the Queen Elisabeth Central Hospital in Blantyre, Malawi, will be asked to participate in this study.

What does the study involve?
Children will be randomly allocated to either the control group, where the mothers will be asked about the stool habits of their child, or to the intervention group, where the healthcare professionals will assess the stool habits using diapers.

What are the possible benefits and risks of participating?
Since healthcare professionals conduct a thorough health check with every child admitted, children are under excellent supervision and receive the best care possible. It is also beneficial for the mothers of the sick children, since they are in close contact with the professionals, which gives them ample of opportunity to ask questions and be reassured that their child is taken care of. There are no risks associated with using diapers in children.

Where is the study run from?
Nutritional Rehabilitation Center of the Queen Elizabeth Central Hospital in Blantyre, Malawi

When is the study starting and how long is it expected to run for?
The study will start in October 2013 and run until January 2014

Who is funding the study?
The study will be funded by the SickKids Foundation, Toronto, Canada

Who is the main contact?
Dr Wieger Voskuijl, MD, PhD

Contact information

Type(s)
Scientific

Contact name
Dr Wieger Voskuijl

Contact details
Queen Elisabeth Central Hospital
Department of Paediatrics
Private Bag 360
Ginney Corner
Blantyre
Malawi
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Stool frequency in Severe Acute Malnutrition: a randomized controlled trial comparing maternal stool recall versus a direct stool observation method using diapers

Acronym
StoolSAM

Study objectives
Stool output as assessed by the maternal/carer recall method is equivalent to a clinical gold-standard assessment using directly observed diapers in children with severe acute malnutrition (SAM).

Ethics approval required
Old ethics approval format

Ethics approval(s)
College of Medicine Research Ethics Committee, University of Malawi, 11/10/2013, P.07/13/1429

Study design
Randomized gold-standard controlled interventional single-centre trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Diagnostic

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied
Severe acute malnutrition in children

Interventions
1. Intervention group: conventional disposable diapers will be put on children and will be checked and changed every two hours by healthcare professionals. Mothers can also request to get the diapers changed within the 2 hours if there was a stool episode.
2. Control group: no intervention

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
1. Observed stool frequency
2. Stool consistency measured with the help of the Bristol stool chart and the Amsterdam paediatric stool chart (watery/loose/normal/bloody)

In the diaper group, diapers will be checked every two hours over a time period of 3 days. The day starts at 8.00 AM, from then on diapers will be checked at 10.00, 12.00, 14.00, 16.00 and 18.00. During the night (between 18.00 and 8.00), the night nurses are instructed to change the diapers whenever necessary (i.e., when there was an episode of stool) and collect those diapers in a bucket. In the control group, mothers are asked every morning during ward rounds (at around 10.00) about the stool episodes during the previous day with the help of a picture chart ('from sunrise to sunset = yesterday', 'from sunset to sunrise = last night', 'since sunrise').

Secondary outcome measures
The mother's opinion on the preferred stool assessment method (disposable diapers or no diapers). This will be assessed after completion of the study, i.e. on the morning after day 3. We are using a scale from 1-5 (1 = strongly prefer diapers, 5 = strongly prefer verbal recall method).

Overall study start date
12/10/2013

Completion date
31/01/2014

Eligibility

Key inclusion criteria
All children admitted to the Nutritional Rehabilitation Unit of the Queen Elisabeth Central Hospital in Blantyre, Malawi (MOYO) aged 6-40 months who meet the WHO and Malawi National Guidelines criteria for severe acute malnutrition (SAM) will be eligible to participate in this study:
1. Marasmus = weight-for-height less than or equal to -3 Z-scores (WHO growth standards) OR a mid-upper-arm circumference of <11.5 cm
2. Kwashiorkor = nutritionally induced bilateral pitting edema

Participant type(s)
Patient

Age group
Neonate

Sex
Both

Target number of participants
120

Key exclusion criteria
1. Children who are already potty trained and therefore do not require diapers
2. Circulatory and respiratory instability as assessed by the consulting physician
3. Severe rash in the genital area

Date of first enrolment
12/10/2013

Date of final enrolment
31/01/2014

Locations

Countries of recruitment
Malawi

Study participating centre
Queen Elizabeth Central Hospital
Blantyre
Malawi
-

Sponsor information

Organisation
The Hospital for Sick Children (Canada)

Sponsor details
c/o Robert Bandsma
555 University Avenue
Toronto
Canada
M5G 1X8

Sponsor type
Hospital/treatment centre

Website
http://www.sickkids.ca/

ROR
https://ror.org/057q4rt57

Funder(s)

Funder type
Charity

Funder Name
SickKids Foundation (Canada)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	07/06/2017		Yes	No