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Oral ranitidine is effective in treating toddler's diarrhea

Submission date	Recruitment status	[_] Prospectively registered
04/08/2016	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
09/08/2016	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
13/10/2022	Digestive System	

Plain English summary of protocol

Background and study aims
Toddler’s diarrhea or chronic non-specific diarrhea of childhood is a common cause of persistent loose stools in children under-five. It has been defined as diarrhea lasting more than 3 weeks in a toddler who has normal weight and height, without being caused by a tummy bug (viral infection). Low-fat diets and the consumption of fruit juices, especially juices high in sorbitol (a type of sweetener) and those with high fructose (fruit sugar) are thought to play a role in this. Changing the diet and reducing the amount the child drinks have been suggested as potential treatments. Other studies have shown that some probiotics (so called ‘good’ bacteria) may also be effective in reducing symptoms. It has been noted however that following a strict diet can be difficult and so a safe medication treatment may be easier. Ranitidine is a medication which is used to lower the amount of acid produced by the stomach. The aim of this study is to investigate the effectiveness of ranitidine and probiotics in the treatment of Toddler’s diarrhea.

Who can participate?
Children aged 1-3 years who have had diarrhea for at least three weeks which is not caused by an infection.

What does the study involve?
Participants are randomly allocated to one of three groups. Children in the first group are given ranitidine by their caregiver once a day for 10 days in the form of dissolvable tablets. Children in the second group are given probiotics by their caregiver once a day for 10 days in the form of a powder that can be made into a liquid solution. Children in the third group are given a placebo (dummy), which consists of vitamin C, by their caregiver once a day for 10 days in the form of dissolvable tablets. For all groups, care-givers of participating children are asked to record the frequency and consistency of the child’s stool after 5, 10 and 30 days.

What are the possible benefits and risks of participating?
Not provided at time of registration

Where is the study run from?
1. University of Nigeria Teaching Hospital (Nigeria)
2. Enugu State University Teaching Hospital (Nigeria)
3. Federal Medical Centre (Nigeria)

When is the study starting and how long is it expected to run for?
May 2016 to October 2019

Who is funding the study?
African Research League (USA)

Who is the main contact?
1. Dr Samuel Uwaezuoke (scientific)
2. Dr Ikenna Ndu (public)

Contact information

Type(s)
Scientific

Contact name
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Type(s)
Public

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
CTS/16/01

Study information

Scientific Title
Short course of daily oral ranitidine versus probiotics as a novel effective treatment for toddler's diarrhea: a multi-centre, double-blind randomized controlled clinical trial

Study objectives
Ranitidine is more effective than probiotics in the treatment of toddler's diarrhea.

Ethics approval required
Old ethics approval format

Ethics approval(s)
University of Nigeria Teaching Hospital Health Research Ethics Committee, 19/05/2016, ref: NHREC/05/01/2008B-FW00002458-1RB00002323

Study design
Multi-centre double-blind three-arm randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

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

Health condition(s) or problem(s) studied
Toddler's diarrhea (chronic non-specific diarrhea of childhood)

Interventions
Participants are randomised to one of three groups, using colour-coded envelopes.

Ranitidine Group: Participants receive dissolvable tablets of ranitidine (3 mg/kg/day), administered daily by caregivers for 10 days.

Probiotic Group: Participants receive probiotics in powdery form for solution, in age-specific doses, administered daily by caregivers for 10 days.
Control Group: Participants receive a placebo in the form of dissolvable tablets of vitamin C (50 mg) administered daily by caregivers for 10 days.

Follow-up/outcome measures: Stool frequency and consistency will be recorded on days 5 and 10. Any adverse drug reactions will be noted on these follow-up days. There will also be a follow-up documentation of stool frequency and consistency at 30 days.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
1. Ranitidine 2. Lyophilized lactic acid bacteria

Primary outcome measure
1. Stool frequency is measured using care-giver's home observation/records on days 5, 10 and 30
2. Stool consistency is measured using care-giver's home observation/records on days 5, 10 and 30

Secondary outcome measures
No secondary outcome measures

Overall study start date
02/05/2016

Completion date
30/10/2019

Eligibility

Key inclusion criteria
1. Age range of 1-3 years
2. Diarrhea lasting 3 weeks or more
3. Characteristic stooling pattern of toddler's diarrhea
4. Absence of pyrexia and signs of dehydration
5. Normal anthropometry
6. Normal findings on stool analysis, microscopy and culture

Participant type(s)
Patient

Age group
Child

Lower age limit
1 Years

Upper age limit
3 Years

Sex
Both

Target number of participants
120

Total final enrolment
40

Key exclusion criteria
1. Signs of dehydration
2. Presence of pyrexia
3. Abnormal anthropometry

Date of first enrolment
30/07/2016

Date of final enrolment
01/03/2019

Locations

Countries of recruitment
Nigeria

Study participating centre
University of Nigeria Teaching Hospital
Ituku-Ozalla
Enugu
Nigeria
400001

Study participating centre
Enugu State University Teaching Hospital
Enugu
Nigeria
400001

Study participating centre
Federal Medical Centre
Owerri

Nigeria
400001

Sponsor information

Organisation
African Research League

Sponsor details
694 Salisbury Street
Worcester
United States of America
01609

Sponsor type
Research organisation

Website
https://www.linkedin.com/groups/8467425

Funder(s)

Funder type
Research organisation

Funder Name
African Research League

Results and Publications

Publication and dissemination plan
To publish results in a reputable journal once data analysis and manuscript write up is completed.

Intention to publish date
30/10/2020

Individual participant data (IPD) sharing plan
The data sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Basic results		31/07/2019	31/07/2019	No	No
Basic results		09/09/2019	09/09/2019	No	No
Results article	results	11/08/2020	14/08/2020	Yes	No
Protocol file			10/10/2022	No	No
Other files	Brief curriculum vitae of co-investigator (AdaAyuk)		13/10/2022	No	No