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Management of severe acute malnutrition in children with sickle cell disease greater than 5 years of age living in northern Nigeria

Project Number
1R21HD097992-01

Contact PI/Project Leader
DEBAUN, MICHAEL
R.Other PIs

Awardee Organization
VANDERBILT UNIVERSITY MEDICAL CENTER

Description

Abstract Text

The overall goal of this feasibility trial is to determine the acceptability of a randomized controlled trial to ascertain the optimal strategy for the treatment of severe malnutrition in children with sickle cell **disease** (SCD) older than 5 years of age. No international standard or evidence-based guidelines exist for the treatment of severe malnutrition (defined as BMI Z-score below −3) in children with SCD. With an expanding pediatric population of more than 75 million in Nigeria, coupled with decreasing childhood **infectious disease**-related mortality, the next **emerging** threats to preventable childhood deaths are non-communicable diseases. Data from our ongoing NIH- funded randomized controlled primary stroke prevention trial in Nigeria (NCT02560935), in which we evaluated children with SCD between 5 and 12 years of age, demonstrated that 29% (230/803) of the cohort met criteria for severe malnutrition. Approximately 92% of the cohort in northern Nigeria identified as having severe malnutrition was below the 5th percentile for weight of children with SCD living in the US, Canada, or Europe. These data indicate older children with SCD living in northern Nigeria are undernourished when compared to children living with SCD in high-resource settings. A potentially unique attribute to treating malnutrition in children with SCD is the use of FDA approved anti-metabolite, hydroxyurea, to prevent vaso-occlusive pain events in children. The beneficial effects of hydroxyurea include, but are not limited to, decreased inflammation and increased hemoglobin levels. Preliminary evidence in our cohort of older children with sickle cell anemia (SCA) in northern Nigeria reveals that moderate fixed dose hydroxyurea (20 mg/kg/day) significantly increases BMI in children with severe malnutrition. We propose a randomized controlled feasibility trial in older children (5 to 12 years of age) with SCA living in northern Nigeria. In preparation for a definitive phase III trial to determine if a nutritional supplement (SoyaPlus) and moderate fixed dose hydroxyurea therapy is superior to a nutritional supplement alone, we will randomly allocate 100 children between 5 and 12 years of age with SCA and severe uncomplicated malnutrition to each of the two arms. In aim 1, we will assess the feasibility (rate of recruitment, retention, and adherence) randomized controlled trial to a 12-week intervention period. We will assess the feasibility of a RCT in children with SCA and severe malnutrition. For aim 2, we will establish the safety protocol to monitor for unknown rates of complications associated with treating malnutrition in children with SCD. To decrease the likelihood of sharing limited food resources in a poor family and to determine the specificity of malnutrition for children with SCD in northern Nigeria, we will screen and treat up to 100 malnourished non-SCD siblings of the trial participants. After completion of this feasibility trial, we will use the acquired knowledge to design a phase III trial to definitively determine the optimal treatment strategy for severe malnutrition in older children with SCD living in Africa, potentially affecting thousands of children in this region.

Public Health Relevance Statement

All global recommendations for treatment of childhood malnutrition are for children less than 5 years of age, and no recommendations have been developed specifically for sickle cell disease. The overall goal of this feasibility clinical study is to identify whether families of children with sickle cell disease and severe malnutrition will agree to participate in a nutritional rehabilitation clinical trial, stay adherent to the protocol, and remain enrolled in the study. We also plan to develop a protocol for identifying potential complications associated with nutritional rehabilitation of children with uncomplicated severe malnutrition guiding the design of future phase III clinical trials.

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Contact PI/Project Leader
DEBAUN, MICHAEL R.
Other PIs

Awardee Organization
VANDERBILT UNIVERSITY MEDICAL CENTER

Antimetabolites Birth Body mass index Canada Cessation of life Child Child Malnutrition Childhood Clinic Clinical Research Clinical Treatment Clinical Trials Communicable Diseases Country Coupled Data **Disease** Dose Enrollment Europe Event FDA approved Family Funding Future Goals Height Hemoglobin concentration result Inflammation International Intervention Knowledge Malnutrition Medical Monitor Neighborhoods Nigeria Nutritional Participant Patients

Read More

Details

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City
NASHVILLE

Country
UNITED STATES (US)

Department Type
Unavailable

Organization Type
Independent Hospitals

State Code
TN

Congressional District
05

Other Information

FOA
PA-18-482

Study Section
Integrative Nutrition and Metabolic Processes Study Section[INMP]

Fiscal Year
2019

Award Notice Date
29-June-2019

Administering Institutes or Centers
EUNICE KENNEDY SHRIVER NATIONAL INSTITUTE OF CHILD HEALTH & HUMAN DEVELOPMENT

DUNS Number
079917897

CFDA Code
865

Project Start Date
01-September-2019

Project End Date
31-August-2021

Budget Start Date
01-September-2019

Budget End Date
31-August-2020

Project Funding Information for 2019

Total Funding
$204,913

Direct Costs
$138,482

Indirect Costs

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1R21HD097992-01	DEBAUN, MICHAEL R.Other PIs	VANDERBILT UNIVERSITY MEDICAL CENTER

2019	EUNICE KENNEDY SHRIVER NATIONAL INSTITUTE OF CHILD HEALTH & HUMAN DEVELOPMENT	$204,913

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Funding IC	FY T
EUNICE KENNEDY SHRIVER NATIONAL INSTITUTE OF CHILD HEALTH & HUMAN DEVELOPMENT	$204

Sub Projects

No Sub Projects information available for 1R21HD097992-01

Publications

No Publications available for 1R21HD097992-01

Patents

No Patents information available for 1R21HD097992-01

Outcomes

The Project Outcomes shown here are displayed verbatim as submitted by the Principal Investigator (PI) for this award. Any opinions, findings, and conclusions or recommendations expressed are those of the PI and do not necessarily reflect the views of the National Institutes of Health. NIH has not endorsed the content below.

No Outcomes available for 1R21HD097992-01

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Contact PI/Project Leader
DEBAUN, MICHAEL
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Awardee Organization
VANDERBILT UNIVERSITY MEDICAL CENTER

News and More

Related News Releases

No news release information available for 1R21HD097992-01

History

No Historical information available for 1R21HD097992-01

Similar Projects

No Similar Projects information available for 1R21HD097992-01

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