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The double burden of malnutrition in Mexican adolescents

Submission date
01/05/2020

Recruitment status
No longer recruiting

Registration date
15/06/2020

Overall study status
Completed

Last Edited
15/09/2022

Condition category
Nutritional, Metabolic, Endocrine

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Major depressive disorder (MDD) and Iron deficiency anemia are two of the three main causes of disability among adolescents worldwide. Additionally, iron plays an important role in the synthesis of neurotransmitters (signaling chemicals found in the brain and nervous system) and in neurological development.

The aim of this study is to examine the association of anemia and iron deficiency with depressive symptoms and self-harm behavior in Mexican adolescent girls.

Who can participate?
Girls aged 12 to 19 years old, who live in urban areas in Northern Mexico

What does the study involve?
Participants will be assessed for anthropocentric measures, pubertal development, hemoglobin levels and iron status (from blood samples), as well as depressive symptoms and self-harm behavior.

What are the possible benefits and risks of participating?
Participants will receive a report of their nutritional status and iron status. At the end of the study participants receive nutritional recommendations and the opportunity to have a free psychological evaluation. This study is not thought to be associated with increased health risks. However, blood drawing occasionally can cause bruising.

Where is the study run from?
Universidad de Monterrey (Mexico)

When is the study starting and how long is it expected to run for?
From September 2018 to March 2019

Who is funding the study?
Universidad de Monterrey (Mexico)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

Study information

Scientific Title
Investigation of the iron status and presence of depressive symptoms and self-harm behavior, and the possible interaction of this association with the gut microbiota, intestinal inflammation and pubertal development in adolescent girls living in Mexico

Acronym
DBM ADOL

Study objectives
Iron deficiency in Mexican adolescents may be associated with the presence of depressive symptoms and self-harm behavior.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 04/07/2018, the Research Ethics Committee of the University of Monterrey (Av. Morones Prieto 4500 Pte, San Pedro Garza Gacia, Nuevo Leon, Mexico 66238; +52 (81) 8215 1212), ref: 04072018-CEI

Primary study design
Observational

Study design
Cross-sectional observational study

Study type(s)
Screening

Health condition(s) or problem(s) studied
Iron deficiency and depressive symptoms

Interventions
Adolescent girls aged 12 to 19 inclusive from public schools were recruited. Written consent was obtained from the adolescents and their parents. The assessment and samples were taken within one visit.

Blood samples were drawn by a trained nurse or a technician in order to assess iron status (SF, BIS and sTfR), and inflammation (CRP, AGP) biomarkers. The serum samples were exported to Germany, where iron and inflammation biomarkers were measured using in-house sandwich enzyme-linked immunosorbent assay in the Vitmin Lab, Germany.

The Six-item Kutcher Adolescent Depression Scale (6-KADS) (LeBlanc, et al., 2002) was used to identify if the adolescent has symptoms of depression. The 6-KADS was developed to assist in the public health and clinical identification of young people at risk for depression.

Intervention Type
Other

Primary outcome(s)
All outcome measures were assessed at a single timepoint.
1. Serum ferritin level measured using in-house sandwich enzyme-linked immunosorbent assay of serum samples
2. Serum transferrin receptor level measured using in-house sandwich enzyme-linked immunosorbent assay of serum samples
3. Depressive symptoms score assessed by the Six-item Kutcher Adolescent Depression Scale (6-KADS)

Key secondary outcome(s)
1. Anemia measured using a Hemocue 201+ portable photometer apparatus to assess hemoglobin in capillary blood
2. Gut microbiota composition in fecal samples assessed by 16s rRNA sequencing. This analysis is on hold as the Microbiology Lab of Wageningen University has suspended activities due to COVID-19.

Completion date
08/03/2019

Eligibility

Key inclusion criteria
1. Adolescent girls aged 12 to 19 inclusive attending public schools.
2. Written consent from the parents or legal guardians
3. Written consent from the adolescents
4. Considered to be in good health

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Other

Sex
Female

Total final enrolment
408

Key exclusion criteria
1. Diagnosis of chronic disease that may affect iron status.
2. History of major surgery in the last month (at the moment of recruitment).
3. Regular use of antibiotics.

Date of first enrolment
04/09/2018

Date of final enrolment
08/03/2019

Locations

Countries of recruitment
Mexico

Study participating centre
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Sponsor information

Organisation
Universidad de Monterrey

Organisation
Wageningen University & Research

ROR
https://ror.org/04qw24q55

Funder(s)

Funder type
University/education

Funder Name
Universidad de Monterrey (UDEM)

Funder Name
Consejo Nacional de Ciencia y Tecnología (National Council of Science and Technology, Mexico)

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated and/or analysed during the current study during this study will be included in the subsequent results publication. Datasets will be shared under request with the reviewers for publication purposes. The use of the datasets generated during this study by a third party can be possible only if Universidad de Monterrey and Wageningen University agree.

IPD sharing plan summary
Published as a supplement to the results publication

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		18/05/2022	15/09/2022	Yes	No