

Survey on management of pediatric constipation

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON26158

Source

NTR

Brief title

CIT

Health condition

Constipation

Sponsors and support

Primary sponsor: FrieslandCampina

Source(s) of monetary or material Support: FrieslandCampina

Intervention

Outcome measures

Primary outcome

Descriptive statistics, regarding different diagnostic criteria used by HCPs in relation to the reported prevalence of constipation

Secondary outcome

Differences in protocols and management techniques between different medical practitioners, based on their country of residence, level of experience, specialization etc.

Study description

Background summary

The incidence of functional constipation varies across various countries in the world. Its reported incidence among children (0-18 years) ranges from around 05-30%. This range could be due to the use of different diagnostic criteria across the year (ie. ROME III vs ROME IV criteria) as well as the use of different stool criteria (Bristol Stool Scale vs Amsterdam Stool Scale).

International guidelines recommend the use of nutritional management for functional constipation especially in toddlers as compared to a pharmacological approach. In addition, the nutrition formulation for managing this issue varies. It includes various functional ingredients such as partially hydrolyzed, prebiotics, probiotics and milk fat.

The survey aims to understand knowledge and practices among healthcare professionals providing primary care in the participating countries in diagnosing and managing constipation in toddlers; and their preference for optimal nutrition solutions. Thus the purpose of this initiative is to get more insight on the subjects and reported differences if any, among low, middle- and high-income countries; and between two types of healthcare professionals (general practitioners and pediatricians).

This protocol describes a survey using electronic data capture and will follow a non-purposive sampling method. It will be distributed via email or whatsapp stating the link to electronic data capture to relevant healthcare professionals (HCP)s and will allow anonymous responses from the participants. The number of respondents in each country is targeted between 100-200 respondents or 5-10% of the number of HCPs in each country in 5-6 countries, with an estimated total sample of around 1000 respondents.

Study objective

1. Different diagnostic criteria are used among primary care providers leading to variation in the estimated prevalence.
2. Management of first-choice for constipation in this age group (pharmaceuticals, nutritional or both) varies among participating countries and various primary health care providers.

Study design

- 1 - it's a cross-sectional survey

Intervention

not applicable (this is electronic survey among HCPs)

Contacts

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Eligibility criteria

Inclusion criteria

Individual practicing health care professionals (HCP)s in participating countries who manage constipation cases in their daily practices. The HCPs can have public or private practices.

Exclusion criteria

Individual practicing health care professionals (HCP)s in participating countries who manage less than 5% of constipation cases in their day-to-day practice.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL
Recruitment status: Pending
Start date (anticipated): 28-05-2021
Enrollment: 1000
Type: Anticipated

IPD sharing statement

Plan to share IPD: No

Ethics review

Positive opinion
Date: 28-05-2021
Application type: First submission

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register ID

NTR-new NL9568

Other Medical Research Ethics Committee, University of Malaya Medical Centre (Kuala Lumpur, Malaysia) : MREC ID NO: 202119-10148

Study results