Federaal Kenniscentrum voor de Gezondheidszorg
Centre Fédéral d'Expertise des Soins de Santé
Belgian Health Care Knowledge Centre

CB-1601

Dietary intervention for newly diagnosed irritable bowel syndrome

Introduction

The aim of the KCE Trials programme is to ensure that high quality research information is produced on the effectiveness, costs and broader impact of health technology in the most efficient way for those who use, manage, provide care in or develop policy for the Belgian healthcare system.

An overview of the selection procedure can be found in the document "Information for candidate sponsors and guidance note for expression of interest" (v1.1), associated with this commissioning brief and available on our website.

Research question

What is the most effective first-line treatment for newly diagnosed irritable bowel syndrome?

1. Intervention: Dietary intervention, to be defined by the applicant.

2. Patient group: Patients with newly-diagnosed irritable bowel syndrome, to be defined by the applicant.

3. Setting: to be defined by the applicant.

4. Control: should include antispasmodic medication, to be further defined by the applicant.

5. Study design: Multicentre, randomised controlled trial, to be defined by the applicant, with or without an internal pilot to test the ability to recruit and randomise patients. If a pilot is included, the criteria to continue or not from pilot to full trial should be specified.

6. Important outcomes: To be defined by the applicant. Outcomes should be patient-centred, measured at appropriate time-points and validated.

Decision problem to be addressed by this research:

Irritable bowel syndrome (IBS) is a common chronic gastrointestinal disorder characterized by fluctuating complaints of abdominal pain or discomfort and an altered bowel habit resulting in diarrhoea or constipation. The prevalence of IBS ranges from 5-18% depending on the clinical setting and the diagnostic criteria used. IBS is associated with depression and anxiety disorders as well as with somatic co-morbidities including fibromyalgia, chronic fatigue syndrome and chronic pelvic pain. Research shows that IBS can result in impaired health-related quality of life and that IBS symptoms have a large impact on work productivity. IBS is also associated with increased health care utilisation and costs (1).

Both antispasmodic medication and dietary interventions have been shown to have some efficacy in improving the symptoms of IBS but their effectiveness has not been compared in a pragmatic, randomised trial.

(1) Ruepert L, Quartero AO, deWit NJ, van der Heijden GJ, Rubin G, Muris JWM. Bulking agents, antispasmodics and antidepressants for the treatment of irritable bowel syndrome. Cochrane Database of Systematic Reviews 2011, Issue 8. Art. No.: CD003460.

KCE TRIALS PROGRAMME

Notes to Applicants

To ensure the highest quality research, the appropriate guidelines and regulations must be followed and KCE recommendations for applicants are provided.

Methodology: for many of the research questions posed by the KCE Trials programme, a randomised controlled trial is the most appropriate method of providing an answer. Suggestions for how a randomised controlled trial could be designed and constructed most efficiently are encouraged.

Quality, ethical and legal: applicants are asked to follow the Declaration of Helsinki and ICH-GCP guidelines and all applicable legislation such as Belgian Law of 7 May 2004 concerning experiments on the human person, when planning their trial. Note that trials involving medicinal products must comply with "The Medicines for Human Use (Clinical Trials) Regulations 2004" and be submitted to the Federal Agency for Medicines and Health Products (FAMHP). The FAMHP website contains the latest information about Clinical Trial regulations.

Inspections by FAMHP to document conformity with GCP requirements and local legislation can take place at any time during the progress of KCE funded studies.

In line with the government's transparency agenda, any contract resulting from this tender may be published in its entirety and made available to the general public.

Clinical Trials Toolkit

General information on the conduct of clinical trials can be found in the Clinical Trials Toolkit. This NIHR resource is designed to help researchers navigate through the complex landscape of setting up and managing clinical trials. Please note that the website is developed for the UK, therefore local regulations and references may not apply in Belgium.

Research networks

The KCE Trials programme expects, where appropriate, that applicants will work with relevant existing research networks.

Making an application

If you wish to submit an Expression of Interest (EOI) on this topic, complete the associated application form available on our website, and submit it (as a PDF) via email to trials"at"kce.fgov.be by **October 18th before 13.00 hours**. Applications received after 13.00 hours on the due date will not be considered.

Applications will be considered by the KCE Trials Board at its meeting during the week of November 14th 2016.

Please read the document "Information for candidate sponsors and guidance note for expression of interest", associated with this commissioning brief and available on our website.

IMPORTANT: For shortlisted EOI, investigators will be given six weeks to submit a full research proposal.