Abstract

MAgnetic Resonance imaging in COeliac disease (MARCO)

Coeliac disease (CD) is an autoimmune disease induced in genetically susceptible individuals after ingestion of gluten and affects 1 in 100 people. The only treatment is a strict gluten-free diet for life. The gold standard diagnostic test is a duodenal biopsy. The small bowel mucosa is primarily affected resulting in progressive degrees of villous inflammation and destruction.

Loss of villi, which absorb fluid, hypertophy of crypts, which produce fluid, and slower small bowel transit result in fluid excess in the small bowel lumen. Until recently it has been difficult to study bowel fluid distribution without invasive techniques such as intubation, which may disturb physiology. Pilot data from a study using a new Magnetic Resonance Imaging (MRI) technique at the University of Nottingham showed that small bowel water content was increased in untreated coeliac disease compared to healthy volunteers.

Combining together all the above, non-invasive MRI techniques in a single, fasting short scanning session could provide novel insights into coeliac disease, the effect of GFD, and the relationship of gastrointestinal function and symptoms.

Hypotheses of the study

Based on our pilot data and on the literature available, this study aims to test the main hypotheses that in adults newly diagnosed with coeliac disease treatment with gluten-free diet (GFD) will:

- 1. Reduce the water content of the fasting small bowel
- 2. Reduce the volume of the fasting colon
- 3. Increase whole gut transit time

Objectives of the study

The specific objectives of the study are therefore to quantify any change following treatment with a GFD in:

- 1. The water content of the fasting small bowel
- 2. Fasting colon volume
- 3. Whole gut transit time

In adults newly diagnosed with coeliac disease using non-invasive MRI

This study will also include a parallel pilot study healthy volunteers (HVs) frequency matched for age (in 20 years bands) and gender to provide descriptive statistics on a likely reference range for the healthy population to inform the design of future studies.

Milestones

Ethics and R&D approval in place.

Start date July 2016: commence recruitment for patients and volunteers.

Magnetic Resonance Imaging – 2 scans 12 months apart with symptom questionnaires, stool samples and hydrogen breath test.

Visit 2 – from July 2017

Duration of study = 36 months.

Duration of study for each participant = approximately 12 months.

Data analysis will be carried out during recruitment and scanning.

April 2018: Close recruitment (or earlier if targets met before then)

Finish second scan on final patient or volunteer by April 2019.

September 2019: complete data analysis

December 2019: finish writing up study.

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