Feasibility study: The effect of the low FODMAP diet on women suffering from endometriosis

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON28996

Source
NTR

Brief title
TBA

Health condition

Endometriosis, low FODMAP diet

Sponsors and support

Primary sponsor: Maxima Medical Centre, Veldhoven
Source(s) of monetary or material Support: Maxima Medical Centre (Veldhoven)

Intervention

Outcome measures

Primary outcome

The primary outcome is the change in abdominal symptoms measured using the Groningen DeFeC questionnaire.

Secondary outcome

The secondary outcome is the change in quality of life measured using the EHP-30 questionnaire

Study description

Background summary

Endometriosis is a benign gynaecological condition defined as the presence of endometrial tissue outside of the uterus with a prevalence of 7-10% within the general population of premenopausal women. Frequent symptoms include chronic inflammation, abdominal pain, dysmenorrhoea and subfertility. 15-22% of the women also present bowel symptoms such as a bloated feeling and changing stool, comparable to the symptoms experienced with irritable bowel syndrome (IBS). Visceral hypersensitivity is a factor that seems to play a role in both endometriosis as IBS. A curative therapy for endometriosis has not been found yet and therefore research into optional therapies focused on symptom control is of great value, with visceral hypersensitivity as a logical target for intervention. A known visceral hypersensitivity targeted therapy for IBS with significant reduction of abdominal symptoms is the low FODMAP diet. FODMAP is an abbreviation of Fermentable Oligosaccharides, Disaccharides, Monosaccharides and Polyols, short-chain carbohydrates found in numerous fruits, vegetables and grains. During the diet the poorly absorbed carbohydrates are eliminated, that otherwise cause an increase in small intestinal water volume and colonic gas production. Doing so, the exacerbation of gastro-intestinal symptoms will reduce and intestinal luminal distension causing abdominal pain and a bloated feeling should be prevented, especially in those with visceral hypersensitivity. Recent literature found a significant reduction in symptoms in women suffering from both endometriosis and IBS after introducing the low FODMAP diet. The common symptoms between endometriosis and IBS suggest that this diet could be a therapy for women only suffering from endometriosis as well.
This study aims to evaluate the effect of the low FODMAP diet on the symptoms of patients with endometriosis.
The primary outcome is the change in abdominal symptoms measured using the Groningen DeFeC questionnaire. The secondary outcome is the change in quality of life measured using the EHP-30 questionnaire. Both questionnaires are to be filled in at the start of the diet, after the elimination period and after the re-introduction period.

Study objective

The hypothesis is that women suffering from endometriosis will benefit from the low FODMAP diet with a significant improvement in their symptoms related to visceral hypersensitivity.

Study design

- At the start of the low FODMAP diet
- After the elimination period (approximately 4 weeks)
- After the re-introduction period (approximately 6 weeks)

Intervention

The low FODMAP diet

Contacts

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Eligibility criteria

Inclusion criteria

Subjects meeting all of the following criteria will be able to participate in the study:
- Premenopausal women (≥ 18 years old)
- Diagnosed with endometriosis by anamnesis, ultrasound, laparoscopy or MRI
- Experiencing abdominal symptoms such as abdominal pain, bloating, flatulence, obstipation, diarrhoea, gurgling, urgency or nausea
- Been prescribed the low FODMAP diet

Exclusion criteria

Subjects meeting any of the following criteria will be excluded from participating in the study:
- Postmenopausal or aged under 18 years old
- Women not able to speak, read or write Dutch
- Gastro-intestinal co-morbidities such as food allergy, Crohn’s disease, Ulcerative Colitis, Coeliac disease

- Currently pregnant

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):	01-11-2019
Enrollment:	20
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Plan description
N/A

Ethics review

Not applicable

Application type:	Not applicable

Study registrations

Followed up by the following (possibly more current) registration

ID: 52456

Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL8022
CCMO	NL71354.015.19
OMON	NL-OMON52456

Study results

Summary results
N/A