THE CUPIDO STUDY: The effect of the multispecies probiotic Ecologic 825 versus placebo in Ulcerative Colitis patients

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To investigate whether a specifically designed multispecies probiotic mixture (ecologic 825®), as adjuvant therapy, can contribute to an improvement of intestinal permeability, microbiota composition, disease activity and inflammatory markers in...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Gastrointestinal inflammatory conditions
Study type	Interventional

Summary

ID

NL-OMON40262

Source
ToetsingOnline

Brief title
CUPIDO study

Condition

- Gastrointestinal inflammatory conditions

Synonym
inflammatory bowel disease (IBD), Ulcerative Colitis (CU)

Research involving
Human

Sponsors and support

Primary sponsor: Wageningen Universiteit

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Gut health, Intestinal permeability, Probiotica, Ulcerative Colitis

Outcome measures

Primary outcome

Main study parameter is intestinal permeability measured by several techniques: the Multi Sugar Absorption test in 24-h urine, zonulin in faeces and in serum.

Secondary outcome

Inflammation will be measured from faecal calprotectin and blood c-reactive protein (CRP) levels. Furthermore samples will be stored to measure cytokine concentrations in serum and to analyse the microbial composition of the faecal samples using the HITchip. For the disease related quality of life the irritable bowel disease questionnaire (IBD-Q) and SF-36 will be used. All parameters will be measured at three time points; t=0, t=6 and t=12 weeks.

Study description

Background summary

The underlying etiology in inflammatory bowel diseases such as Ulcerative Colitis is not yet fully understood. Studies suggest a relation between higher intestinal permeability and aberrant changes of the epithelium. Dysbiosis of the intestinal microbiota might be the cause. Probiotics may restore the balance of the intestinal microbiota. In theory this could improve intestinal permeability and therefore reduce disease activity and maintain remission in patients with Ulcerative Colitis.

Study objective

To investigate whether a specifically designed multispecies probiotic mixture (ecologic 825®), as adjuvant therapy, can contribute to an improvement of intestinal permeability, microbiota composition, disease activity and inflammatory markers in ulcerative colitis.

Study design

12-wk placebo-controlled randomized double-blind intervention with 2 parallel arms.

Intervention

Patients will receive either two daily dosages of 3 g of Ecologic® 825 or two daily doses of 3 g of the placebo, containing only the carrier material (both produced by Winclove Probiotics).

Study burden and risks

The lactic acid bacteria in the mixture carry the European Union Qualified Presumption of Safety (QPS) status. No side effects are expected. The probiotic mixture is available on the Dutch market under the name PRO.IB. The product has been used in pouchitis patients, without adverse effects. Measurements are restricted to blood sampling, urine and faeces collection at 3 time points. The probiotic treatment might be beneficial resulting in a better gut health which could prolong the remission period and improve disease related quality of life.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- Diagnosed Ulcerative Colitis (left sided UC or pancolitis)
- Age 18-65 (because microbiotia change at older age)
- Stable disease activity (clinical remission with CRP levels <10mg/L) as measured at baseline
- Mesalazine medication as only medication for UC with a maximum intake of 2.4 g/day

Exclusion criteria

- History of intestinal surgery that might interfere with the outcome of the study
- Diabetes Mellitus (medication dependent)
- Current use of antibiotics
- Current use of corticosteroids (30 days prior to the first baseline measurement).
- Treatment with other medication besides mesalazine (NSAIDs, topical or systemic steroids, immunosuppressive drugs or aspirin) one week prior the first baseline measurement.
- Use of other pre- and probiotics and not willing to stop these 2 weeks before the intervention period
- Hypersensitivity or allergy to milk protein, soy protein and gluten
- Alcohol abuse (male more than 14 servings a week, female more than 7 servings a week)
- Female patients: currently pregnant or breast-feeding or intending to become pregnant during the study
- Patients foreseen to need GI surgery during the study period
- Patients with a history of cancer

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	02-12-2014
Enrollment:	40
Type:	Actual

Ethics review

Approved WMO Date:	06-03-2014
Application type:	First submission
Review commission:	METC Wageningen Universiteit (Wageningen)
Approved WMO Date:	06-10-2014
Application type:	Amendment
Review commission:	METC Wageningen Universiteit (Wageningen)

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
CCMO	NL46674.081.13