

Calprotectin in patients with perianal fistulas: the CANALS study

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We recently published a retrospective observation study in which we showed that: • Faecal calprotectin can discriminate between cryptoglandular and Crohn's perianal fistulas, even in the absence of endoscopic inflammation and • In Crohn's disease...

Ethische beoordeling	Niet van toepassing
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON28117

Bron

Nationaal Trial Register

Verkorte titel

CANALS study

Aandoening

Crohn's disease perianal fistulas and cryptoglandular perianal fistulas

Ondersteuning

Primaire sponsor: none

Overige ondersteuning: none

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

- Determine the diagnostic accuracy of faecal calprotectin for differentiating between active Crohn's disease perianal fistulas and cryptoglandular perianal fistulas

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale: Cryptoglandular (CG) and Crohn's disease (CD) perianal fistulas represent separate entities, both with regard to etiopathogenesis as well as treatment strategy. Differentiating both entities on clinical grounds can be difficult and in a considerable number of patients endoscopy is required to rule out CD. Still, diagnostic accuracy is limited by the fact that perianal fistulas may be the first manifestations of CD. In a retrospective observational study, we recently demonstrated that faecal calprotectin (FC) – a non-invasive surrogate marker of inflammation – can discriminate between CG and CD perianal fistulas. Furthermore, the diagnostic accuracy of FC to detect luminal inflammation in CD patients with an active perianal fistula appeared to be decreased. Especially specificity of FC was low, as one-third of patients with an elevated FC value ($>250\text{mcg/g}$) had endoscopically quiescent disease.

Objective: Determine the diagnostic accuracy of FC for (i) differentiating between active CD perianal fistulas and CG perianal fistulas and (ii) predicting the presence of intestinal inflammation in CD patients with an active perianal fistula

Study design: Prospective single center cross-sectional study

Study population: 70 patients with an active perianal fistula who require surgical examination under anesthesia at the outpatient surgery center; 35 patients with a CD perianal fistula and 35 with a CG perianal fistula

Main study parameters/endpoints:

Primary objectives

- Determine the diagnostic accuracy of faecal calprotectin for differentiating between active Crohn's disease perianal fistulas and cryptoglandular perianal fistulas

Secondary objective

- Determine the diagnostic accuracy of faecal calprotectin for the presence of active intestinal inflammation in CD patients with an active perianal fistula
- Determine local calprotectin production in an active fistula tract determined by fistula fluid and scrapings calprotectin concentration
- Determine the association between the anatomical nature of the fistula tract (simple vs complex) and faecal calprotectin and fistula fluid and scrapings calprotectin concentrations
- Determine the association between the epithelialization status of the fistula tract and faecal calprotectin and fistula fluid calprotectin concentrations
- Determine the correlation between the Perianal Disease Activity Index (PDAI) and faecal calprotectin concentration
- Determine the correlation between calprotectin concentration in faeces and fistula fluid
- Determine the correlation between calprotectin concentration in fistula fluid and fistula scraping
- Determine the correlation between calprotectin concentration in faeces and fistula scraping

Nature and extent of the burden and risks associated with participation, benefit and group relatedness: For this study patients only undergo procedures as part of standard clinical care. During examination under anesthetics, additional biomaterial will be collected: faeces, fistula fluid and fistula tract scraping. To acquire this biomaterial rinsing of the fistula tract is followed by scraping of the fistula tract using a curette surgical instrument (to create a fresh

tract). Both procedures are part of general clinical practice. A scoop of faeces will be collected from the rectum which does not burden the patient. In the CD group, intestinal inflammation is assessed in all patients with an abdominal ultrasound which will only focus at the gastrointestinal tract. This procedure is non-invasive, painless, quick and without risks. We therefore consider this procedure not to burden the patient.

Doel van het onderzoek

We recently published a retrospective observation study in which we showed that:

- Faecal calprotectin can discriminate between cryptoglandular and Crohn's perianal fistulas, even in the absence of endoscopic inflammation and
- In Crohn's disease patients with an actively draining perianal fistula, specificity of faecal calprotectin to predict intestinal ulcers is low and faecal calprotectin values should be interpreted with caution. The underlying hypothesis for the aforementioned results comes down to the loss of calprotectin via the fistula tract into the faeces. Due to distinct underlying etiopathogenesis, active CG fistulas might not produce calprotectin in a similar amount as active CD fistulas. Hence FC could be used to discriminate these two entities. Furthermore due to the loss of calprotectin from within the fistula tract towards the intestinal lumen, the diagnostic accuracy of FC for the presence of intestinal inflammation might be decreased.

Onderzoeksopzet

cross sectional.

Onderzoeksproduct en/of interventie

N/A

Contactpersonen

Publiek

Amsterdam UMC, location AMC
Toer Stevens

0205665584

Wetenschappelijk

Amsterdam UMC, location AMC
Toer Stevens

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Crohn's perianal fistulas:

- Patients ≥ 16 years old
- Established Crohn diagnosis, based on a combination of history, physical examination, family history, laboratory tests, endoscopy tests including histopathologic examination of mucosal biopsies, imaging studies and occasionally intraoperative findings
- Active perianal fistula as defined by spontaneous drainage or drainage upon gentle finger compression
- Clinical indication for surgical examination or intervention under anesthesia at discretion of the treating physician at the outpatients surgery center of the Amsterdam UMC, location AMC
- Written informed consent

Cryptoglandular perianal fistulas:

- Patients ≥ 16 years old
- Established diagnosis of a cryptoglandular perianal fistula, based on a combination of history and physical examination and supplemented by the prior exclusion of Crohn's disease by at least one previous endoscopy
- Active perianal fistula as defined by spontaneous drainage or drainage upon gently finger compression
- Clinical indication for surgical examination or intervention under anesthesia at discretion of the treating physician at the outpatients surgery center
- Written informed consent

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

Crohn's perianal fistulas:

- Age < 16 years at inclusion
- Perianal abscess > 2 cm on MRI and/or clear clinical signs of an perianal abscess that requires surgical incision and drainage.
- Perianal hidradenitis suppurativa
- Clinical signs of an infectious gastroenteritis
- Patients with an ileostomy or colostomy
- No internal opening during surgical examination

Cryptoglandular perianal fistulas:

- Age < 16 years at inclusion
- Perianal abscess
- Perianal hidradenitis suppurativa
- Clinical signs of an infectious gastroenteritis
- No internal opening during surgical examination

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Parallel
Toewijzing:	N.v.t. / één studie arm
Blinding:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland	
Status:	Werving gestart
(Verwachte) startdatum:	26-03-2019
Aantal proefpersonen:	70
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nee

Toelichting

N/A

Ethische beoordeling

Niet van toepassing

Soort: Niet van toepassing

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL7673
Ander register	METC AMC : W19_070 # 19.109

Resultaten

Samenvatting resultaten

N/A