

Efficacy of Platelet Rich Stroma as an addition to the surgical treatment of Crohn's perianal fistulas

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Addition of Platelet Rich Stroma in the surgical treatment of Crohn's perianal fistulas improves radiographic healing.

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON26497

Bron

NTR

Verkorte titel

TBA

Aandoening

Crohn's disease; Perianal fistula

Ondersteuning

Primaire sponsor: None

Overige ondersteuning: None

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Clinical closure combined with radiographic closure of the fistula tract after surgical

intervention at 6 months. Clinical closure of fistula tract is defined as closure of the external openings at physical examination. Radiographic closure is defined as the amount of percent decrease in luminal activity measured by hyper intensity on pelvic T2-weighted MRI.

Toelichting onderzoek

Achtergrond van het onderzoek

This study aims to assess the efficacy of additional injection of Platelet-Rich Stroma in the surgical treatment of Crohn's perianal fistulas. A prospective case series will be set up that will include patients with Crohn's fistulas who undergo PRS treatment during fistula surgery. The primary outcome is defined as combined clinical and radiographic closure healing on postoperative MRI. Follow-up MRI will be performed after clinical closure of the fistula tract, preferably within 6 months postoperatively.

This study was already submitted in January 2019 by the researcher. However, due to the transition to the new website of the NTR the study is registered in 2020.

Doel van het onderzoek

Addition of Platelet Rich Stroma in the surgical treatment of Crohn's perianal fistulas improves radiographic healing.

Onderzoeksopzet

Follow-up until 12 months posteratively

Contactpersonen

Publiek

Erasmus MC
Jeanine Arkenbosch

06-50033976

Wetenschappelijk

Erasmus MC
Jeanine Arkenbosch

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Patients with Crohn's perianal fistulas, defined as one or more perianal fistula tracts in patients with previously endoscopic or histologic confirmed Crohn's disease.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- Presence of pelvic sepsis or abscesses at the time of study entry.
- Perianal fistula is a rectovaginal fistula.
- Any oncological event in the patients history in the previous five years.
- Any other medical condition that in the judgement of the investigator could interfere with their optimal participation in the study or produce a significant risk to the patient.

Onderzoeksopzet

Opzet

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

Deelname

Nederland	
Status:	Werving gestart
(Verwachte) startdatum:	01-11-2018
Aantal proefpersonen:	40
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum: 02-03-2020

Soort: Eerste indiening

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	NL8417
Ander register	METC Erasmus MC : MEC-2019-0425

Resultaten