

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

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON26497

Source

NTR

Brief title

TBA

Health condition

Crohn's disease; Perianal fistula

Sponsors and support

Primary sponsor: None

Source(s) of monetary or material Support: None

Intervention

Outcome measures

Primary outcome

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.

Secondary outcome

- Surgical data
- Length of stay in the hospital
- Postoperative complications (infection / bleeding) of the perianal and liposuction sites
- Time to clinical healing. Clinical healing will be defined as closure of the internal and external opening at physical examination
- Need of re-intervention and/or readmissions within 6 months follow up (depending on available time to follow-up)

Study description

Background summary

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.

Study objective

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

Study design

Follow-up until 12 months posteratively

Contacts

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Eligibility criteria

Inclusion criteria

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.

Exclusion criteria

- 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.

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:	Recruiting
Start date (anticipated):	01-11-2018

Enrollment: 40
Type: Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion
Date: 02-03-2020
Application type: First submission

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
NTR-new	NL8417
Other	METC Erasmus MC : MEC-2019-0425

Study results