

Is the use of bloodplatelets effective in the treatment of difficult fistulas related to the anal sfincter?

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The use of platelets in addition to mucosa advancement flap in the treatment of complex peri-anal fistula will reduce the recurrence rate of these fistulas.

Ethische beoordeling	Niet van toepassing
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON20536

Bron

NTR

Aandoening

platelet rich plasma, peri-anal fistulas
trombocytenrijk plasma, peri-anale fistels

Ondersteuning

Primaire sponsor: Maastrich University Medical Center

adress: P.Debyelaan 25 6229 HX Maastricht

phonenummer: 043-387 65 43

Overige ondersteuning: Biomet

adress: Toermalijnring 600

3316 LC Dordrecht

The Netherlands

phone number: +31622981737

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Recurrent fistulas. The surgeon or doctor in the outpatient clinic will decide if there is a recurrent fistula or not. In case of doubt a MRI will be made.

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale:

Closure of the internal opening is the most accepted standard procedure in the treatment of peri-anal fistulas. The mucosal advancement flap is considered as golden standard. In one out of the three patients mucosal flap repair fails. Possible causal factors are incomplete clearance of pus and debris, incomplete closure of the internal opening, inappropriate host response in patients with risk factors like smoking or diabetes. Platelet derived growth factors may facilitate closure of the internal opening, especially in patients with impaired wound healing.

Objective:

The use of autologous platelet rich plasma (PRP) as an adjunct to the staged mucosal advancement flap to achieve a better closure rate of complex peri-anal fistula's.

Study design:

Randomised, multicenter trial.

Study population:

Patients with complex cryptoglandular peri-anal fistula's.

Intervention:

Injection of PRP in the curreted fistula track under the mucosal flap.

Main study parameters/endpoints:

Recurrence rate, post-operative pain, continence, quality of life.

Nature and extent of the burden and risks associated with participation, group relatedness:

Because autologous blood is used, no extra risk are expected.

Doel van het onderzoek

The use of platelets in addition to mucosa advancement flap in the treatment of complex peri-anal fistula will reduce the recurrence rate of these fistulas.

Onderzoeksopzet

2, 4, 16, 24, 52 and 104 weeks.

Onderzoeksproduct en/of interventie

This study consists of two arms. One arm will be treated conventionally with a mucosa advancement flap, with a seton procedure in advance.

The other arm will be treated with a mucosa advancement flap after a seton procedure and additionally PRP will be added to this group of patients. For the PRP we will need to take 55 millilitres of blood of the patient. This blood will be centrifuged into PRP. This PRP will be injected into the fistula, then the mucosa advancement flap will be created.

Contactpersonen

Publiek

R. Wouda
Maastricht
The Netherlands
0613232756

Wetenschappelijk

R. Wouda
Maastricht
The Netherlands
0613232756

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Age 18-80 years;
2. Able to understand informed consent;
3. Complex peri-anal fistula.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Pregnancy;
2. Local malignancy;
3. Crohn's disease/ulcerative colitis;
4. A traumatic or iatrogenic lesion;
5. Trombocytopenia;
6. Splenomegaly;
7. Bleeding disorders;
8. Hematologic malignancies.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blinding:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland	
Status:	Werving gestopt
(Verwachte) startdatum:	01-04-2011
Aantal proefpersonen:	120
Type:	Werkelijke startdatum

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	NL2301
NTR-old	NTR2830

Register

Ander register
ISRCTN

ID

MEC MUMC : 10-1-082
ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten

van der Hagen SJ, baten CG, Soters PB, van Gemert WG. Autologous platelet derived growth factors(platelet rich plasma) as an adjunct to mucosal advancement flap in high cryptoglandular peri-anal fistulae: a pilot study. Colorectal Dis. 2009 Jul 3.