

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

No registrations found.

<b>Ethical review</b>	Not applicable
<b>Status</b>	Recruitment stopped
<b>Health condition type</b>	-
<b>Study type</b>	Interventional

## Summary

### ID

NL-OMON20536

### Source

NTR

### Health condition

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

## Sponsors and support

**Primary sponsor:** Maastrich University Medical Center

adress: P.Debyelaan 25 6229 HX Maastricht

phonenumber: 043-387 65 43

**Source(s) of monetary or material Support:** Biomet

adress: Toermalijnring 600

3316 LC Dordrecht

The Netherlands

phone number: +31622981737

## Intervention

## Outcome measures

### Primary outcome

1 - Is the use of bloodplatelets effective in the treatment of difficult fistulas re ... 5-05-2025

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.

### **Secondary outcome**

1. Visual analogue scale (VAS-score);
2. Quality of life (SF-36 questionnaire);
3. Incontinence (Vaizey score).

## **Study description**

### **Background summary**

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.

### **Study objective**

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.

### **Study design**

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

### **Intervention**

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.

## **Contacts**

### **Public**

R. Wouda  
Maastricht  
The Netherlands  
0613232756

### **Scientific**

R. Wouda

## Eligibility criteria

### Inclusion criteria

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

### Exclusion criteria

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.

## Study design

### Design

Study type:	Interventional
Intervention model:	Parallel

Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

## Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	01-04-2011
Enrollment:	120
Type:	Actual

## Ethics review

Not applicable	
Application type:	Not applicable

## 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	NL2301
NTR-old	NTR2830
Other	MEC MUMC : 10-1-082
ISRCTN	ISRCTN wordt niet meer aangevraagd.

## Study results

### Summary results

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.