Use of platelet rich plasma(PRP) as an adjunct in the treatment of high peri-anal fistulas.

Published: 12-03-2012
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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 high peri-anal fistula*s.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Anal and rectal conditions NEC
Study type	Interventional

Summary

ID

NL-OMON43622

Source
ToetsingOnline

Brief title
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Condition

- Anal and rectal conditions NEC
- Gastrointestinal therapeutic procedures

Synonym
fistula

Research involving
Human

Sponsors and support

Primary sponsor: Medisch Universitair Ziekenhuis Maastricht
Source(s) of monetary or material Support: Biomet

Intervention

Keyword: peri-anal fistula, PRP

Outcome measures

Primary outcome

Main study parameters/endpoint primary: recurrence rate

Secondary outcome

Main study parameters/endpoints secundary: post-operative pain, continence,

quality of life.

Study description

Background summary

Use of platelet rich plasma (PRP) as an adjunct in the treatment of high peri-anal fistulas. 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 tree 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 high peri-anal fistula*s. Study design: randomised, multicenter trial. Study population: patients with high cryptoglandular peri-anal fistula*s. Intervention: injection of PRP at 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

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 high

peri-anal fistula*s.

Study design

Study design: randomised, multicenter trial.

Intervention

Intervention: injection of PRP at the curreted fistula track under the mucosal flap.

Study burden and risks

The possible complications associated to treatment are complications which can be epxected by a vena punction like pain, deep venous trmobosis and scar formation. Until now no complications are described for the use of PRP.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

no bias to sex, age 16-80 years, able to understand informed consent, high peri-anal fistula

Exclusion criteria

-inability to fullfill follow-up criteria
-pregnant
-local malignancy
-Crohn*s disease/Ulcerative colitis
-patients with a traumatic/iatrogenic lesion
-Trombocytopenia
- Splenomegaly

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	26-04-2012
Enrollment:	120
Type:	Actual

Ethics review

Approved WMO Date:	12-03-2012
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	24-08-2012
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	26-08-2013
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	01-11-2013
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	17-09-2015
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	28-09-2015
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	30-12-2015
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO	

Date:	07-04-2016
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	13-06-2016
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

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
ClinicalTrials.gov	NCT01615302
CCMO	NL33967.068.10