Antibiotic treatment following surgical drainage of perianal abscess: a double-blind, placebo-controlled, randomized trial.

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This study has been transitioned to CTIS with ID 2024-517233-40-00 check the CTIS register for the current data. The objective of this trial is to establish if adding antibiotic treatment to surgical drainage of perianalabscess results in less...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Gastrointestinal inflammatory conditions
Study type	Interventional

Summary

ID

NL-OMON54272

Source
ToetsingOnline

Brief title
ATLAS trial

Condition

- Gastrointestinal inflammatory conditions
- Ancillary infectious topics

Synonym
fistula, fistula in ano

Research involving
Human

Sponsors and support

Primary sponsor: heelkunde
Source(s) of monetary or material Support: ZonMw

Intervention

Keyword: antibiotics, perianal abscess, perianal fistula, surgical drainage

Outcome measures

Primary outcome

Primary outcome measure is development of a perianal fistula. A perianal fistula is diagnosed based on findings from physical examination. An external opening with or without serosanguilent discharge is considered a fistula. In case of doubt an endoanal ultrasonography or MRI is performed.

Secondary outcome

Secondary outcome measures are quality of life at 12 months measured with the EQ-5D-5L with Dutch rating. Further: in-hospital direct and indirect costs (measured with IPCQ and iMCQ) and out-of hospital postoperative costs, need of repeated drainage, patient related outcome (PRO) and clinical outcome measures. Patient-related outcomes are complaint reduction assessed by a Proctology specific validated patient-related outcome measure (PROM) this was recently developed and validated at Proctos Clinic (Vander Mijnsbrugge). Operatie data, klinische

uitkomsten (complicaties, day of discharge, complications, readmission,

dureation of absence of work).

Study description

Background summary

Perianal fistula is a burdening disease with an annual prevalence of 2/100.000 in the Dutch population.
Treatment is often difficult and in case of high complex fistula more than 50% of patients undergoes more
than 2 operations with still variable results. Every year, in the Netherlands, more than 5000 operations are
carried out for perianal fistula. Consequences for social and work life is considerable and therefore presents
an economic burden. More than 90% of crypto-glandular fistulas originate from anorectal abscess (Sainio).
Despite adequate drainage of anorectal abscess up to 83% recurs or results in an anal fistula, the majority
developing within 12 months (Oliver). Meticulous preoperative diagnosis and concomitant antibiotics are
attempts to reduce this undesirable course but evidence of its effect is scarce. There is some evidence that
gut derived bacteria play a role in development of a perianal fistula (Hamadani, Fielding). Up till now it is not
common practice to routinely administer antibiotics. A systematic review of 6 studies found a decrease of
incidence of anal fistula development when surgical treatment of perianal abscess is accompanied by
antibiotics (Mocanu). However, this review includes 6 studies of which most have a retrospective nature
and only 2 are randomized controlled trials. International guidelines addressing treatment of perianal
abscess recommend drainage and in case of immunosuppression or systemic illness addition of antibiotics
(Vogel, Malik); level of evidence is low (2 C). The Dutch Guideline does not specifically address treatment
of perianal abscess. Further high quality studies are required to clarify the effect of antibiotic treatment in
addition to drainage of perianal abscess. Reports of costs and cost-effectiveness of treatments for patients
with anal fistula are scarce. Only one recent Swedish study investigated disease-associated costs and

concluded that the burden on society is high which justifies all attempts to reduce occurrence (Lundqvist).
Prevention by treating perianal abscess adequately would contribute in this attempt. A trial comparing
efficiency of adequate drainage of perianal abscess followed by postoperative antibiotics vs drainage
followed by placebo drugs is warranted.

Study objective

This study has been transitioned to CTIS with ID 2024-517233-40-00 check the CTIS register for the current data.

The objective of this trial is to establish if adding antibiotic treatment to surgical drainage of perianal
abscess results in less perianal fistulas.

Study design

The study concerns a double-blind, placebo-controlled, randomized, multicenter trial with treatment of
perianal abscess by surgical drainage alone or combined with antibiotic treatment.

Intervention

Patients were randomly allocated to 1 of 2 groups (antibiotics or placebo). The antibiotic group received 7
days of oral metronidazole (500 mg every eight hours) and ciprofloxacin (500 mg every twelve hours) in
addition to surgical drainage. The other group received surgical drainage and postoperatively identical
placebo tablets prepared by the pharmacology department of Amsterdam University Hospital during 7 days.
Surgical drainage is performed by a colorectal surgeon or resident under general or local anesthesia. The
patient is placed in lithotomy position and the rectum is first examined. The abscess is incised and
adequately drained. The abscess cavity is debrided. The rectum is checked for an internal opening. The
wound is left open for secondary healing. When possible pre-or peroperative diagnostics will be done by
either (endo-)ultrasonography or MRI.

Study burden and risks

Questionnaires at 5 different time points - baseline, 1 week, 3 months, 6 and 12 months postoperative. (5 x 10 minutes). Extra visit at the outpatient clinic at 12 months.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

- Men and women aged 18 years or older
- Presenting for the first time with a perianal abscess
- Eligible for e-mail questionnaires
- Sufficient understanding of the Dutch written language (reading and writing)
- Obtained written informed consent

Exclusion criteria

-a coexistent perianal fistula,
-secondary or recurrent perianal abscess,
-presence of an internal fistula opening,
-any additional surgical procedure performed during the same session,
-previous (peri)anal surgery,
-inflammatory bowel disease,
-history of radiation of the pelvic area,
-anorectal malignancy,
-immunodeficiency,
-kidney failure, eGFR <30ml/min
-valvular heart disease,
-pregnancy or lactation,
-antibiotic prophylaxis indicated for another reason,
-immunosuppressive medication at the time of surgery,
-allergy to metronidazole or ciprofloxacin,
-not able or trouble with swallowing pills
-concomitant use of:
o Tizanidine, theophylline, clozapine, olanzapine, pirfenidone, carbamazepine, agomelatine (these are all CYP1A2 substrates, ciprofloxacin is an inhibitor)
o Amiodarone, erythromycin, sotalol, azithromycin, citalopram, escitalopram, flecainide, fluconazole, haloperidol >5mg/day, methadone, ondansetron (concerning prolonged QT interval in combination with ciprofloxacin)
o Lithium (can cause toxic levels with metronidazole)
o Lopinavir/ritonavir, ritonavir capsules, temsirolimus, disulfiram (antabuse), mebendazole (can cause serious side effects, confusion and psychosis in combination with metronidazole)
o Corticosteroids (in combination with ciprofloxacin higher risk of tendinitis and tendon rupture).

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	23-12-2021
Enrollment:	298
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	ciprofloxacin
Generic name:	ciprofloxacin
Registration:	Yes - NL intended use
Product type:	Medicine
Brand name:	Flagyl
Generic name:	Metronidazole
Registration:	Yes - NL intended use

Ethics review

Approved WMO Date:	22-03-2021
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	03-05-2021
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	06-05-2021
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	11-03-2022
Application type:	Amendment

Review commission:	METC Amsterdam UMC
Approved WMO Date:	31-03-2022
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	19-05-2022
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	03-06-2022
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	23-09-2022
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	01-10-2022
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	24-04-2023
Application type:	Amendment
Review commission:	MEC Academisch Medisch Centrum (Amsterdam) Kamer G4-214 Postbus 22660 1100 DD Amsterdam 020 566 7389 mecamc@amsterdamumc.nl
Approved WMO Date:	05-05-2023
Application type:	Amendment

Review commission:	MEC Academisch Medisch Centrum (Amsterdam) Kamer G4-214 Postbus 22660 1100 DD Amsterdam 020 566 7389 mecamc@amsterdamumc.nl

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
EU-CTR	CTIS2024-517233-40-00
EudraCT	EUCTR2020-004449-35-NL
CCMO	NL75540.018.20