LITA trial: A randomized controlled trial of ligation of the intersphincteric fistula tract versus transanal advancement flap repair

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Aim of the present study is to investigate whether LIFT or TAFR is the preferable treatment for high transsphincteric fistulas-in-ano of cryptoglandular origin.

Ethical review	Not approved
Status	Will not start
Health condition type	Anal and rectal conditions NEC
Study type	Observational invasive

Summary

ID

NL-OMON37916

Source
ToetsingOnline

Brief title
LITA trial

Condition

- Anal and rectal conditions NEC
- Gastrointestinal therapeutic procedures

Synonym
Anal fistula; Fistula-in-ano

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Colorectal surgery, Ligation of the intersphincteric fistula tract, Perianal fistula, Transanal advancement flap repair

Outcome measures

Primary outcome

Surgery time.

Secondary outcome

- Postoperative pain-recovery

- Postoperative complications

- Hospital stay and resumption of work

- Impairment of fecal continence

- Quality of life

- Cost-effectiveness from a healthcare and societal perspective

Study description

Background summary

Fistulotomy is the only fistula treatment that actually works most of the time. A major drawback of this procedure is the need for sphincter division with subsequent continence disturbances. Therefore fistulotomy is not appropriate for patients with a transsphincteric fistula, passing through the upper or middle third of the external anal sphincter. The principal goal in the treatment of high transsphincteric fistulas is healing without impaired continence. In contrast to fistulotomy, transanal advancement flap repair (TAFR) provides a more useful tool to minimize sphincter damage. However, it has become clear that this procedure fails in one of every three patients. Until now, no predictive factors for failure have been identified. In a previous study the outcome of repeat flap repair was examined in 26 patients, who encountered a failure after the initial procedure. In all these patients complete healing of the advancement flap was noticed, except at the site of the

original internal opening. This remarkable clinical finding and the lack of predictive factors for failure has made the question whether ongoing disease in the remaining tract contributes to persistence of the fistula after flap repair. Most of the remaining tract is located in the intersphincteric plane near the origin of the fistula. Recently, ligation of the intersphincteric fistula tract (LIFT) has been introduced as a new sphincter preserving procedure. Rojanasakul was the first to describe this new technique. He observed primary healing of the fistula in 94 percent of his patients. Another report from Malaysia also revealed high healing rates, exceeding those obtained with the current sphincter saving techniques. However, recent reports from the USA showed more modest results, indicating that the LIFT procedure, like the flap repair, fails in one of every three patients. Flap repair is rather demanding, whereas LIFT seems to be more easy to perform. We assume that this simple procedure is associated with less postoperative pain, shorter hospital stay and faster resumption of work. Therefore we questioned whether LIFT would be an attractive alternative for TAFR in the treatment of high transsphincteric fistulas and could replace TAFR as the treatment of choice. To investigate this we plan to start a randomized control trial.

Study objective

Aim of the present study is to investigate whether LIFT or TAFR is the preferable treatment for high transsphincteric fistulas-in-ano of cryptoglandular origin.

Study design

Randomized controlled trial.

Study burden and risks

The burden and risks associated with participation is limited to one of the two surgical techniques. The number of site visits and physical examinations is the same as in the current standard protocol. One additional anal manometry will be done in all patients 3 months postoperatively. Anal manometry is necessary to identify anal sphincter defects. Participants are asked to fill in quality of life questionnaires (SF-36, EQ-5D and FIQL) and an impairment of fecal continence questionnaire (RFISI) before surgery, at 1, 2 and 8 weeks postoperatively and 6 months postoperatively. Participants are asked to give a pain score using the visual analogue scale at day 1, 2, 3, 4, 5, 6 and 7 and at week 2 and 8 postoperatively.

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

Patients with a transsphincteric fistula of cryptoglandular origin, passing through the upper or middle third of the external anal sphincter.;Age: 18-75 years.

Exclusion criteria

Patients with a fistula of cryptoglandular origin other than described in the inclusion criteria;Patients with a transsphincteric fistula of cryptoglandular origin, passing through the upper or middle third of the external anal sphincter, in whom the fistula is associated with intersphincteric horseshoe extension;Patients with a rectovaginal fistula ;Patients with inflammatory bowel disease (Crohn*s disease and/or Colitis Ulcerosa)

Study design

Design

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

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	50
Type:	Anticipated

Ethics review

Not approved

Date:	02-08-2012
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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
CCMO	NL39678.078.12