Plan Overview

A Data Management Plan created using DMPonline

Title: HollAND trial: comparison of rubber band ligation and haemorrhoidectomy in patients with symptomatic haemorrhoids grade III: study protocol for a multicentre, randomized controlled trial and cost-utility analysis

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Affiliation: Other

Funder: ZonMw (Nederlands)

Template: Data management ZonMw-template 2019

Project abstract:

Introduction Haemorrhoidal disease is one of the most common anorectal disorders which affects nearly half of the general population. Treatment of grade III haemorrhoids consists initially of conservative measures followed by rubber band ligation and haemorrhoidectomy when unsuccessful. Given the current guidelines and numerous modalities the obvious question which needs to be answered is which treatment is the best for grade III haemorrhoids. There is a need for evaluating treatment from the patient’s point of view and transparency in surgical and non-surgical treatment outcome. Methods and analysis This multicentre, randomized controlled, non-inferiority trial with cost-utility analysis compares haemorrhoidectomy with rubber band ligation. Patients aged 18 years and older with symptomatic haemorrhoids grade III are recruited. Primary outcome measure is quality of life at 24 months measured with the EQ-5D-5L and in-hospital (in)direct costs and out-of-hospital postoperative costs. A key secondary outcome is recurrence at one year post procedure. Secondary outcomes are complaint reduction with proctology specific patient-reported outcome measurements (Haemorrhoid Severity Score, ProctoPROM, PROM-HISS, vaizey score), resumption of work, pain and complication rates. Data are collected at seven different time points. Standard post procedural care is followed. A sample size has been calculated using a one sided alpha of 0.025 and a power of 80% with a standard deviation of 0.15 and a non-inferiority limit of 0.05. With stratification by centre and to adjust for 10% loss to follow up the total sample size will be 360 patients in total (180 per group). Data will be analyzed according to the intention-to-treat and the per-protocol principle. Ethics and Dissemination The protocol has been approved by the Medical Ethics Review Committee of the Amsterdam University Medical Centres, location AMC. Findings will be disseminated in peer-reviewed journals and presented at conferences, whether they are positive, negative or inconclusive. Trial registration number NCT04621695, NTR8020 Strengths and limitations of this study - This study addresses a knowledge gap regarding the optimal treatment of grade III haemorrhoids. - Outcomes are not only based on clinical outcomes but also proctology specific patient-reported outcome measurements and cost-utility. - As it is an evaluation of existing standard care, both Milligan-Morgan and Ferguson technique as well as RBL are not further standardized. - It will prove to be challenging counselling patients to participate in a RCT, given the choice between invasive and non-invasive treatment.

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Copyright information:

HollAND trial: comparison of rubber band ligation and haemorrhoidectomy in patients with symptomatic haemorrhoids grade III: study protocol for a multicentre, randomized controlled trial and cost-utility analysis

1. General features of the project and data collection

1.1 Project leader contact details

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1.2 I have composed my DMP with the assistance of a data stewardship (or management) expert. List his or her name, function, organisation/department, phone number and email address.

- The expert is not connected to my department or institution (please explain his/hr expertise related to data stewardship)

Trialbureau Zorgevaluatie Nederland

1.3 In collecting data for my project, I will do the following:

- Generate new data

1.4 In my research, I will use:

- A combination of quantitative and qualitative data

1.5 I will be reusing or combining existing data, and I have the owner's permission for that.

- No, I will not be reusing or combining existing data

1.6 In collecting new data, I will be collaborating with other parties.

- Yes, we have reached agreements on the user rights of the data used in the project
- Yes, I will collect the new data in conjunction with other researchers or research groups

This is a multicentre trial, with several sites. The Proctos Kliniek is the sponsor. A clinical trial agreement will be made for the participating centres.

1.7 I am a member of a consortium of 2 or more partners. Clear arrangements have been made regarding data management and intellectual property. (also consider the possible effect of changes within the consortium on issues of data management and intellectual property)

- Yes, I am a member of a consortium of 2 or more partners, but clear arrangements have not (yet) been made regarding data

management and intellectual property (please explain)

Clear agreements will be made.

1.8 I can give an estimate of the size of the data collection; specifically, the number of participants or subjects (“n=”) in the collection and its size in GB/TB

- Yes (please specify)

N=360, The size of GB is not yet known but is will probably be around 50MB.

1.9 The following end products I will make available for further research and verification (please elaborate briefly)

- (Several versions of) processed data
- Documentation of the research process, including documentation of all participants
- Raw data
- Syntaxes

1.10 During the project, I will have access to sufficient storage capacity and sites, and a backup of my data will be available. (please elaborate briefly)

- Yes, I will make use of an external provider's services for storage and backup of my data

We will make use of Castor.

2. Legislation (including privacy)

2.1 I will be doing research involving human subjects, and I am aware of and compliant with laws and regulations concerning privacy sensitive data.

- Wet op de Geneeskundige Behandelingsovereenkomst (Medical Treatments Contracts Act)
- The Wet Medisch-Wetenschappelijk Onderzoek met Mensen (WMO, or Medical Research (Human Subjects) Act) applies to my project; I will have it reviewed by a Medical Research Ethics Committee. In addition I will comply with the Kwaliteitsborging Mensgebonden Onderzoek (Quality Assurance for Research Involving Human Subjects)
- Yes, I will involve human subjects in my research. I will comply with the Algemene Verordening Gegevensbescherming (AVG)

2.2 I will be doing research involving human subjects, and I have (a form of) informed consent from the participants for collecting their data.

- Yes, and this informed consent allows for the reuse of data (note that in the Code of Conduct for Medical Research, ‘reuse’ is also referred to as ‘further use’)
- Yes (please describe the form this consent takes)

Written informed consent

2.3 I will be doing research involving human subjects, and I will protect my data against misuse.

- Yes, the data will be pseudonymised. (please explain how this will be done, and by which organisation) and

Using a enrollment log which is only accessible for the local researchers of the participating centers.

2.4 I will stick to the privacy regulations of my organisation

- Yes

3. Making data findable

3.1 The data collection of my project will be findable for subsequent research. E.g., on a catalogue, a web portal, or through the search enginge of the repository (note: this is key item 3, which you should report to ZonMw at the end of your project).

- No, I have not yet chosen an archive or catalogue/web portal

Via Leading the Change

3.2 I will use a metadata scheme for the description of my data collection (note: this is key item 7, which you should report to ZonMw at the end of your project).

- No, I have not yet chosen a metadata scheme

3.3 I will be using a persistent identifier as a permanent link to my data collection (note: this is key item 1, which you should report to ZonMw at the end of your project).

- Yes, I will be using the DOI code

4. Making data accessible

4.1 Once the project has ended, my data will be accessible for further research and verification.

- Yes, after an embargo period (please explain)

3 months embargo due to publishing

4.2 Once the project has ended, my data collection will be publicly accessible, without any restrictions (open access).

- No, there will be access restrictions to my data collection (please explain)

A request must be made at Data Access Committee (DAC)

4.3 I have a set of terms of use available to me, which I will use to define the requirements of access to my data collection once the project has ended (please provide a link or persistent identifier; also note that this is a key item 4, which you should report to ZonMw at the conclusion of your project).

- Not yet, my institution will draft a set of terms of use with the help of a legal advisor

4.4 In the terms of use restricting access to my data, I have included at least the following:

- Agreements on methodology
- Whether or not the data set may be linked with another data set (for reasons of privacy)
- The manner in which the data set can be accessed
- The reimbursement of costs, for example in obtaining the data

5. Making data interoperable

5.1 I will select a data format, which will allow other researchers and their computers (machine actionable) to read my data collection (note: this is key item 5, which you should report to ZonMw at the end of your project).

- Yes (please specify)

Data will be exported from Castor to spss/excel/access/cvs/txt/sas/R*'r

5.2 I will select a terminology for recording my data (e.g., code, classification, ontology) that allows my dataset to be linked or integrated with other datasets (note: this is key item 6, which you should report to ZonMw at the conclusion of your project).

- Yes, metadata standard (please specify)

Castor

5.3 I will be doing research involving human subjects, and I have taken into account the reuse of data and the potential combination with other data sets when taking privacy protection measurements.

- Yes, the participants have given their permission for reuse of the data, and the data have been pseudonymised

6. Making data reusable

6.1 I will ensure that the data and their documentation will be of sufficient quality to allow other researchers to interpret and reuse them (in a replication package).

- I will perform quality checks on the data to ensure that they are complete, correct and consistent (please explain)

Data monitoring using a monitorplan

6.2 I have a number of selection criteria, which will allow me to determine which part of the data should be preserved once the project has ended. (see also question 1.9 and 6.1)

- Yes

6.3 Once the project has ended and the data have been selected, I can make an estimate of the size of the data collection (in GB/TB) to be preserved for long-term storage or archival.

- Not yet (please explain)

6.4 I will select an archive or repository for (certified) long-term archiving of my data collection once the project has ended. (note: this is a key item, which you should report to ZonMw at the conclusion of your project)

- Not yet

We will store our data in the local IT facility at our institution, than the data set is curated, retrievable and accessible

6.5 Once the project has ended, I will ensure that all data, software codes and research materials, published or unpublished, are managed and securely stored. Please specify the period of storage.

- Yes, in accordance with VNSU guidelines (please specify the number of years)

Storage for 15 years

6.6 Data management costs during the project and preparations for archival can be included in the project budget. These costs are:

- Unknown (please explain)

Costs will be made for database development, castor, monitoring and datamanagement; the exact amount is not yet known

6.7 The costs of archiving the data set once the project has ended are covered.

- Not yet (please explain)