'To scope or not to scope' - Reducing oesophagoduodenoscopies for uncomplicated dyspepsia: a randomised controlled trial

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Primary:To evaluate the superiority of a patient-centred, education based, clinical strategy to reduce the volume of endoscopies for dyspepsia in patients over 18 years of age without alarm symptoms, referred for OGD through open-access endoscopy...

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

Summary

ID

NL-OMON47304

Source
ToetsingOnline

Brief title
Reducing oesophagoduodenoscopies for uncomplicated dyspepsia

Condition

- Gastrointestinal disorders

Synonym
Dyspepsia, gastric complaints

Research involving
Human

Sponsors and support

Primary sponsor: Radboud Universitair Medisch Centrum

Source(s) of monetary or material Support: ZonMW

Intervention

Keyword: Dyspepsia, E-learning, Oesophagogastroduodenoscopy, RCT

Outcome measures

Primary outcome

The main study endpoint is the difference between the two study arms in proportion of patients receiving direct OGD after the initial visit to the endoscopy clinic, out of the total number of patients referred for open-access endoscopy. OGDs performed at any time in the study after initial successful intervention , will still be considered successful intervention (intention-to-treat).

Secondary outcome

The difference between the change scores of the two study arms on the following three parameters: Health-related anxiety, severity of upper GI symptoms and quality of life. These will be assessed using a questionnaire at the initial visit to the endoscopy clinic and after 8 weeks

The proportion of patients that received the e-learning and nevertheless received OGD in the 8 weeks after the initial visit, out of the total number of patients receiving the e-learning

Educational value of the e-learning. This will be tested through a knowledge test integrated in the e-learning and administered before and after the

e-learning

Study description

Background summary

Upper gastrointestinal (GI) symptoms, such as dyspepsia without alarm symptoms, are highly prevalent in the general population. Lifestyle modifications and medication can reduce symptoms in most patients. Guidelines state that oesophagogastroduodenoscopy (OGD) is only indicated in a selected high risk group. In spite of these guidelines, OGD referrals for dyspepsia without alarm symptoms are still substantial, subjecting patients to unnecessary risks and causing a burden on healthcare costs. Therefore a strategy is needed to reduce the volume of OGDs in dyspepsia without alarm symptoms.

Study objective

Primary:
To evaluate the superiority of a patient-centred, education based, clinical strategy to reduce the volume of endoscopies for dyspepsia in patients over 18 years of age without alarm symptoms, referred for OGD through open-access endoscopy compared to usual care

Secondary:
1. To determine whether a reserved policy on OGDs combined with a strategy to increase patient knowledge and self-care is non-inferior to early OGD in terms of health-related anxiety, severity of upper GI symptoms and quality of life
2. To evaluate the percentage of patients receiving OGD in spite of the education, in the 12 weeks after the initial visit.
3. To determine whether patients will be able to answer questions about the recognition and management of dyspeptic symptoms more correctly after completion of the e-learning, compared to before the e-learning.the educational value of the e-learning

Study design

General
The proposed study is a multicentre, randomised (see chapter 5.2), controlled superiority trial, consisting of two parallel groups and a primary endpoint of the proportion of patients receiving OGD. The two groups will comprise an intervention arm and control arm. Superiority of the primary endpoint will be tested.

Study setting

Four hospitals in the Netherlands will be included; the Canisius-Wilhelmina Ziekenhuis (Nijmegen), VieCuri Medisch Centrum (Venlo), Jeroen Bosch Ziekenhuis (JBZ) and Ziekenhuis Gelderse Vallei (Ede), all with open-access endoscopy option available. The population referred to these hospitals is representative for the general Dutch population in terms of employment rate and marital status, have a slightly lower perception of health, percentage of nicotine abuse and income and slightly higher percentage of alcohol intake, obesity and contact with GP(14)

Baseline measurement
A baseline measurement will be done for each participating centre over the 12 months prior to study commencement. The number of OGD referrals and procedures will be determined through a retrospective assessment.

Intervention
Patients in the intervention arm will receive oral and written information about the study. They will be informed about the limited asset of OGD in dyspepsia and the possibilities of lifestyle modifications. They will then be offered a web-based e-learning module instead of OGD. The e-learning module will contain educational material and questionnaires. Questionnaire data will be extracted from the e-learning module. For more detailed information see chapter on *investigational product* (Chapter 5). Patients will be advised to return to the GP if symptoms persist and the GP will receive advice about management and treatment optimalisation of each individual patient.

Control
Patients in the control arm will receive oral and written information about the study and *care as usual*, i.e. OGD. They will also receive the same questionnaires as the intervention group.

Post-intervention and control measurements
Post-intervention, the difference (%) between the number of patients referred for OGD and those that received OGD in both groups will be determined.

Follow-up
Eight weeks after intervention we will administer questionnaires. Literature suggests that antisecretory drugs should be tried for 1-2 months(15) and a delay in diagnosis when no alarm symptoms exist, has been shown not to effect outcome(9) justifying an eight week follow-up.
After either intervention or OGD, patients will directly return to the standard of care of the general practitioner.

Intervention

Patients will be offered e-learning instead of endoscopy. The e-learning will contain educational material and questionnaires. Questionnaire data will be

extracted from the e-learning.

Study burden and risks

Benefits of specific education of patients on upper GI symptoms and treatment are possibly a reduced amount of inappropriate OGDs. This consequently results in reduced exposure to the risk of serious adverse events and reduced costs. The potential harm of a reserved policy on upper GI endoscopies is a possible persisting feeling of fear or uncertainness which might otherwise have been taken away by a OGD. This could result in more frequent visits to the primary healthcare centre. It has however been stated before that OGD does not reassure patients long term. Also, however inappropriate, incidentally a clinically significant endoscopic finding can be done during such endoscopies. These incidental findings might not be found when OGD is averted. In addition, completing the e-learning and questionnaires will consume time of patients.

Contacts

Public
Radboud Universitair Medisch Centrum

Oudlaan 4
Utrecht 3515GA
NL
Scientific
Radboud Universitair Medisch Centrum

Oudlaan 4
Utrecht 3515GA
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

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

Inclusion criteria

Patients are eligible for inclusion when they meet the following criteria at randomisation:
- Age *18 years
- Reported upper gastrointestinal symptoms in the past 6 months
- Referred for OGD
- Guidelines for referral not met
- Signed informed consent

Exclusion criteria

Patient who fulfil the criteria for OGD acoording to the Dutch college of General Practitioners (NHG) guidelines ('Maagklachten') and NICE guidelines on *Upper gastrointestinal tract cancers*.;- Family history of gastric- or oesophageal cancer (at least one first or second grade family member with a malignancy at the age of 50 or younger)
- Diseases or circumstances that will most likely impair understanding of the e-learning
- Any argument provided by a patient*s own GP stating the urge of OGD, notwithstanding the guidelines

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Diagnostic

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-10-2017
Enrollment:	414
Type:	Actual

Ethics review

Approved WMO Date:	27-06-2017
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	23-01-2018
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	28-03-2018
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	20-11-2018
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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	NL60056.091.17

Study results

Results posted: 02-04-2021

First publication
31-03-2021