REDucing Unneeded EndoScopies

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON25468

Source
Nationaal Trial Register

Brief title
REDUES

Health condition

Dyspepsia, upper gastrointestinal malignancy

Sponsors and support

Primary sponsor: Jeroen Bosch Hospital stipendium
Source(s) of monetary or material Support: Jeroen Bosch Hospital (annual stipend; year 2018) and the Netherlands Organisation for Health Research and Development (ZonMw), grant no. 80-83920-98-400.

Intervention

Outcome measures

Primary outcome

Number of normal, non-clinically relevant and clinically relevant findings at OGD by age group

Secondary outcome

- Incidence of upper GI malignancy
- Accuracy of age and symptoms on malignancy detection

Study description

Background summary

In the Netherlands, dyspepsia is the indication for over 20% of all performed oesophagogastroduodenoscopies (OGD) [ref]. Though the procedure of choice to diagnose mucosal abnormalities in the upper GI tract, the diagnostic yield of OGDs in patients with uncomplicated dyspepsia is limited. Even the presence of alarm symptoms alone in dyspeptic patients without risk factors does not justify endoscopic evaluation, as the pooled sensitivity and specificity of alarm symptoms is a mere 67% and 66% respectively.
As early as in 1988 it was stated that dyspeptic patients under 45 could safely receive pharmacological treatment, instead of endoscopic evaluation. The years that followed were marked by increased awareness of excessive use of OGDs and subsequently more stringent guidelines for OGD indications. The American College of Gastroenterology and the Canadian Association of Gastroenterology together updated the guidelines on dyspepsia in 2017, raising the age limit for recommended OGD to 60 years of age (previously 55 years), and not suggesting OGD under the age of 60, regardless of the presence of alarm symptoms. The Dutch guideline for General Practitioners on the other hand still recommends OGD for all patients with alarm symptoms and recommends to consider OGD in those over 50 years of age with new onset dyspepsia. These Dutch guidelines do not stroke with the current reserved attitude towards the use of OGD for dyspepsia. This may be because Dutch data on the prevalence of malignancy in dyspeptic patients undergoing OGD per age group is dated and cannot be expected to properly represent the current situation. In order to decide whether or not to follow the ACG and CAG in raising the age limit for suggested OGD, new data is needed. This could then subsequently be used as a cornerstone for future guidelines updates and clinical trials in this field. Contributing to the decision whether or not to raise the age limit should be the one year survival of patients with upper gastrointestinal malignancies diagnosed at OGD, since early detection of cancer may justify OGD at younger age, if that would result in a significant improvement of survival.The aim of this study will therefore be to provide data on the current diagnostic yield of OGD in dyspeptic patients per age group. This will be investigated through a multicentre, database study of open-access endoscopies, performed in 3 medical centres in the period 2013-2016.

! This study was already submitted in June 2018 by the researcher. However, due to the transition to the new website of the NTR the study is registered in 2020.

Study objective

We hypothesise that diagnostic yield of OGD is low if a 50-years age cut-off is used.

Study design

1/1/2013 - 31/12/2016

Contacts

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Eligibility criteria

Inclusion criteria

- Open-acces upper gastrointestinal endoscopies performed between 1/1/2013 and 31/12/2016 in the Canisius-Wilhelmina Hospital, Nijmegen, VieCuri Medical Centre, Venlo, and Jeroen Bosch Hospital, 's Hertogenbosch

Exclusion criteria

- Surveillance or follow-up endoscopies
- Endoscopy in patients with known gastrointestinal malignancy
- Endoscopy in patients with known anatomical abnormality
- Emergency endoscopies (performed within 24 hours after referral)

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other

Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	06-06-2017
Enrollment:	1500
Type:	Actual

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	21-05-2020
Application type:	First submission

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
NTR-new	NL8631

Register ID

Other	METC Arnhem-Nijmegen and local ethics committees : reference no. 2017-3411 [Radboudumc], A18-0792 [Jeroen Bosch Hospital], 303 [Viecuri Medical Centre], 021-2017 [Canisius Wilhelmina Hospital]).

Study results