Optimization of Duodenal tIssue ResEction aCquisiTion (DIRECT) study

Published: 05-12-2022
Last updated: 07-04-2024

To evaluate the quality of cold snare biopsies specimens of duodenal mucosa tissue in patients undergoing an upper gastrointestinal interventional endoscopy under deep sedation to improve histological assessment of duodenal mucosa in general and...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Other condition
Study type	Observational invasive

Summary

ID

NL-OMON53392

Source
ToetsingOnline

Brief title
DIRECT study

Condition

- Other condition

Synonym
duodenal tissue acquisistion, obtaining gut tissue

Health condition

Duodenum weefsel

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W,Uit geld reeds in bezit van onderzoeksgroep

Intervention

Keyword: Duodenal, Endoscopy, Tissue

Outcome measures

Primary outcome

Feasibility of acquiring adequate histological samples, including

- Endoscopic cold snare biopsy of duodenal tissue

- Fixation of the specimens

- Slicing and staining of the samples

Ability to acquire adequate orientation of the tissue slides of the duodenal

mucosa, in order to

- Measure length of villi and crypts

- Measure thickness of the mucosal layers

- Determine density of certain stained cells/proteins.

Size and depth of cold snare biopsy tissue slides of the duodenal mucosa.

Weight of the cold snare tissue.

Secondary outcome

Not applicable.

Study description

Background summary

The evaluation of histological changes in tissue obtained by duodenal biopsies has proven to be very difficult due to lack of orientation in acquired histological slides. We also learned that duodenal biopsies are too small and superficial to reliably assess histological changes in duodenal mucosa and submucosa. Currently, we collect small cold snare biopsies from the duodenum to be able to fully assess the duodenal mucosa. However, we still experience problems in the orientation of these mucosal resections. When sections are made, the specimens are curled, cut tangential and artefacts develop. This makes it still impossible to make a proper assessment of duodenal mucosa. Therefore we would like to optimize the process of obtaining, storing, processing and staining the duodenal mucosal tissue samples after cold snare biopsies.

Study objective

To evaluate the quality of cold snare biopsies specimens of duodenal mucosa tissue in patients undergoing an upper gastrointestinal interventional endoscopy under deep sedation to improve histological assessment of duodenal mucosa in general and specifically for future DMR studies.

Study design

Single site (Amsterdam UMC) open-label study
- No randomization
- Patients that are planned to undergo an upper gastrointestinal interventional endoscopy under deep sedation with propofol sedation.
- Obtaining 2 additional duodenal mucosal cold snare biopsies during this esophageal ESD or EMR procedure.
- Patients follow-up by standard of care, no study follow-up.

Study burden and risks

There is no extra burden for the participants, at most that they are sedated a little longer. The additional risk consists of undergoing 2 cold snare biopsies, preceded by submucosal lifting.

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 are eligible, when they are already scheduled to undergo an upper gastrointestinal interventional endoscopy under deep sedation (propofol) at the Amsterdam UMC.

Exclusion criteria

A potential subject who meets any of the following criteria will be excluded from participation in this study:
- Previous GI surgery that could affect the ability to reach the duodenum via endoscopy, such as Bilroth 2, Roux-en-Y gastric bypass, or other similar procedures or conditions
- History of duodenal inflammatory diseases including Crohn*s Disease and Celiac Disease

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	10-01-2023
Enrollment:	30
Type:	Actual

Ethics review

Approved WMO Date:	05-12-2022
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	03-07-2023
Application type:	Amendment
Review commission:	METC Amsterdam UMC

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	NL82178.018.22