# Intra-operative Pancreatoscopy in Patients with Intraductal Papillary Mucinous Neoplasm (IPMN)

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1. To demonstrate the added value of intraoperative pancreatoscopy in patients undergoing partial pancreatic resection for the treatment of Intraductal Papillary Mucinous Neoplasm (IPMN) as it pertains to detection of discontinuous (skip) lesions in…

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| **Ethical review** | Approved WMO |
| **Status** | Recruitment stopped |
| **Health condition type** | Other condition |
| **Study type** | Observational invasive |

## Summary

### ID

NL-OMON54888

**Source**
ToetsingOnline

**Brief title**
IOP-IPMN

### Condition

- Other condition
- Miscellaneous and site unspecified neoplasms benign
- Gastrointestinal therapeutic procedures

**Synonym**
Intraductal Papillary Mucinous Neoplasm (IPMN)

**Health condition**

Intraductaal papillair mucineus neoplasma (IPMN)

**Research involving**

Human

## Sponsors and support

**Primary sponsor:** Boston Scientific Cooperation International
**Source(s) of monetary or material Support:** Boston Scientific Corporation

## Intervention

**Keyword:** Intraductal Papillary Mucinous Neoplasm (IPMN), Intra-operative pancreatoscopy

## Outcome measures

### Primary outcome

Rate of detection of discontinuous (skip) lesion(s) along the Main Pancreatic Duct (MPD) of patients with IPMN using intraoperative pancreatoscopy based on visual impression of IPMN and/or pancreatoscopy guided biopsies.

### Secondary outcome

1. Technical success: Ability to (a) advance the pancreatoscope along the entire MPD length or until clinically needed, (b) to visualize the potential lesion(s) or (c) to obtain a tissue sample with SpyBite* where applicable

2. Serious adverse events related to the intra-operative pancreatoscopy procedure and/or device

3. Recurrence of IPMN within 5 years post-surgery evaluated with regular MRI or alternative radiological method (CT/EUS/other)

4. Comparison of visual and biopsy diagnosis based on exploration with SpyGlass* of the resected specimen

5. Inter-observer correspondence of visual impression of IPMN, based on

intra-operative impression and on review of recorded intraoperative

pancreatoscopy images/videos

# Study description

### Background summary

The recurrence rate of resected malignant IPMN has been reported to be 15-40% compared to only 8% of resected non-malignant IPMN. Among patients with resected malignant IPMN, those who have tumor recurrence have a significantly poorer survival rate compared to those who do not have recurrence. Multiple studies have shown that the degree of dysplasia present at the resection margin is a significant and independent factor contributing to recurrence after resection of malignant IPMN.

However, the lack of evidence-based recommendations for surgical decision making - specifically, how much additional pancreatic tissue to resect in case of dysplasie at the resection margin - is one of the major clinical challenges pancreatic surgeons face. Moreover, even when a clear resection margin is obtained, lesions along the duct within the remnant that are not continuous with the primary IPMN lesion may be missed. Studies show that approximately 20% of patients of resected IPMN cysts are discovered to have these lesions, referred to as skip (discontinuous) lesions. Identifying such lesions intra-operatively may alter the surgical plan and lead to extension of resection or sparing of suspicious tissue.

### Study objective

1. To demonstrate the added value of intraoperative pancreatoscopy in patients undergoing partial pancreatic resection for the treatment of Intraductal Papillary Mucinous Neoplasm (IPMN) as it pertains to detection of discontinuous (skip) lesions in the remnant pancreas

2. To generate a hypothesis for a subsequent randomized control trial

### Study design

Prospective, Multi-center, Non-Randomized, Consecutive series Observational study

**Study burden and risks**

Patients participating in the study will undergo intraoperative pancreatoscopy, in addition to standard pancreatic resection for IPMN. The follow-up after the operation will be according to local standards, and no additional reviews, admission, outpatient clinic visits are required. Therefore, patients participating in this study will have a minor burden associated with participation.

There are no reported complications associated with IOP in the literature and the use of IOP reduces many of the risk factors associated with conventional per oral pancreatoscopy (ie during surgery can drain contrast medium, in surgery can control any bleeding if necessary). Therefore, the risk of participating in this study is very low (almost negligible).

# 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

Patient scheduled for surgery for suspected MD-IPMN or Mixed IPMN within 4-6 weeks of enrollment
Diameter of pancreatic main duct >5mm on pre-operative MRI or CT
Written informed consent from patient to participate in the study, including compliance with study procedures

### Exclusion criteria

Contraindication for pancreatoscopy
Age: less than 18 years
Pregnant women

## Study design

### Design

**Study type:** Observational invasive

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|---|---|
| Masking: | Open (masking not used) |
| Control: | Uncontrolled |
| Primary purpose: | Diagnostic |

### Recruitment

NL

| | |
|---|---|
| Recruitment status: | Recruitment stopped |
| Start date (anticipated): | 26-06-2020 |
| Enrollment: | 20 |
| Type: | Actual |

### Medical products/devices used

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|---|---|
| Generic name: | SpyGlass Digitial System II;SpyGlass Discover and SpyBite Max |
| Registration: | Yes - CE intended use |

# Ethics review

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| Approved WMO Date: | 05-03-2020 |
| Application type: | First submission |
| Review commission: | METC Amsterdam UMC |
| Approved WMO Date: | 21-12-2020 |
| Application type: | Amendment |
| Review commission: | METC Amsterdam UMC |
| Approved WMO Date: | 09-04-2021 |
| 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 | NL70652.018.19 |