# Percutaneous intratumoural holmium microspheres brachytherapy for patients with pancreatic cancer; a single centre, prospective safety and feasibility study

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To test the feasibility and safety of minimally invasive CT-guided percutaneous holmium-166 microsphere brachytherapy in patients suffering from irresectable pancreatic cancer.

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| **Ethical review** | Approved WMO |
| **Status** | Recruiting |
| **Health condition type** | Malignant and unspecified neoplasms gastrointestinal NEC |
| **Study type** | Interventional |

## Summary

### ID

NL-OMON51321

**Source**
ToetsingOnline

**Brief title**
SLOTH-2a

### Condition

- Malignant and unspecified neoplasms gastrointestinal NEC
- Endocrine neoplasms malignant and unspecified
- Gastrointestinal therapeutic procedures

**Synonym**
pancreatic adenocarcinoma, Pancreatic cancer

**Research involving**
Human

## Sponsors and support

**Primary sponsor:** Radboud Universitair Medisch Centrum
**Source(s) of monetary or material Support:** Ministerie van OC&W,Terumo

## Intervention

**Keyword:** Holmium microspheres, Microbrachytherapy, Minimal Invasive, Pancreatic cancer

## Outcome measures

### Primary outcome

The main endpoint is to establish the feasibility and safety of CT-guided percutaneous intratumoural implantation of HoMS in irresectable pancreatic adenocarcinoma. Feasibility is established by evaluating the average tumour absorbed dose in Gray (Gy) calculated on SPECT. Safety is evaluated using the Common Terminology Criteria for Adverse Events (CTCAE v5.0).

### Secondary outcome

As exploratory endpoints, tumour response (RECIST1.1), microsphere distribution by MRI and CT, pain (NRS) and Quality of Life is evaluated. Total follow-up is 16 weeks.

# Study description

### Background summary

Pancreatic cancer holds one of the worst prognosis of all known malignancies. In over 80% of cases curative resection of the tumour is not possible due to metastases or local advancement, and only intensive palliative chemotherapy or best-supportive care remains. Patients suffering from locally advanced pancreatic cancer may benefit from local ablative or radiation therapies which may improve local tumour control, pain, quality of life and survival. Minimally invasive intratumoural injection of beta-minus (β-) emitting 166-holmium microspheres (micro brachytherapy) may be feasible for patients with locally

irresectable pancreatic cancer.

### Study objective

To test the feasibility and safety of minimally invasive CT-guided percutaneous holmium-166 microsphere brachytherapy in patients suffering from irresectable pancreatic cancer.

### Study design

This is a single centre, prospective, safety and feasibility study with a medical device in a maximum of 6 patients.

### Intervention

A radioactive medical device will be implanted by CT-guided percutaneous injection. The medical device in question are beta-minus (β-) and gamma (γ) emitting holmium-166 poly(L-lactic acid) microspheres (166Ho-PLLA-MS, HoMS) in a 0.1% Pluronic or cellulose based suspension.

### Study burden and risks

Patients eligible for inclusion need to undergo additional imaging, one CT and MRI before intervention, one SPECT, CT and MRI within 1 week after intervention, one CT and MRI 16 weeks after intervention. The patients undergo additional CT during HoMS implantation, which increases the radiation dose; however, this is negligible when compared with the absorbed tumour-dose from the HoMS. Patients are required to fill in questionnaires before and after intervention, which is combined, if possible, in a second trial (PACAP, NCT03513705) to prevent overlap in patient burden. Patients who receive the study intervention have an increased risk of pancreatitis, gastro-intestinal bleeding, fistula, jaundice or local infection. This may cause discomforts including fatigue, nausea, emesis, diarrhoea, abdominal pain or fever. Symptomatic discomforts can be treated if possible. Clear benefits are the fulfilment of a treatment wish and the contribution to the development of a new treatment for pancreatic cancer in future patients. Although benefits cannot be assured and depend on multiple factors, benefits may include: pain reduction, increased life expectancy, increased local tumour control, tumour shrinkage, downstaging and resection.

## 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

1. Female or male aged 18 years and over.
2. Pathologically proven pancreatic adenocarcinoma, also known as pancreatic ductal adenocarcinoma.
3. Patient is deemed ineligible for surgical resection of the pancreatic cancer:
a. in accordance with consensus at the multidisciplinary meetings/discussions,
b. and/or the patient refuses to undergo surgical resection out of personal choice
4. Life expectancy of 16 weeks or longer.
5. World Health Organisation (WHO) Performance status 0-1
6. One or more measurable pancreatic tumours of at least 20 mm in the longest diameter by spiral CT or MRI according to the Response Evaluation Criteria in Solid Tumours (RECIST) 1.1 criteria.
7. Negative pregnancy test for women of childbearing potential.

## Exclusion criteria

1. Radiation therapy within the last 4 weeks before the start of study therapy.

2. Chemotherapy within the last 2 weeks before the start of study therapy.
3. Calcifications in the pancreas or tumour that are highly expected to obstruct the needle tract
4. Any unresolved toxicity >= grade 3 from the National Cancer Institute (NCI), Common Terminology Criteria for Adverse Events (CTCAE version 5.0) from previous anti-cancer therapy.
5. Leukocytes < 3.0 109/l and/or platelet count < 75 109/l.
6. Kidney failure: Creatine > 165 µmol/l and/or eGFR < 60 ml/min/1,73m2
7. Significant cardiac event classification of heart disease >=2 within 3 months before entry, or presence of cardiac disease that in the opinion of the Investigator increases the risk of ventricular arrhythmia.
8. Patient is deemed ineligible for implantation of 166Ho by an expert panel (surgeon, nuclear medicine physician, interventional radiologist, radiologist, and researcher) due to tumour anatomy, nearby structures, patient status or a combination.
9. Pregnancy or breast feeding (women of child-bearing potential).
10. Patients suffering from psychic disorders that make a comprehensive judgement impossible, such as psychosis, hallucinations and/or depression.
11. Patients who are declared incompetent.

# Study design

## Design

**Study type:** Interventional

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

## Recruitment

NL

| | |
|---|---|
| Recruitment status: | Recruiting |
| Start date (anticipated): | 11-05-2023 |
| Enrollment: | 6 |
| Type: | Actual |

## Medical products/devices used

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|---|---|
| Generic name: | Intratumoural holmium-166 microspheres |
| Registration: | Yes - CE outside intended use |

# Ethics review

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| Approved WMO Date: | 16-11-2022 |
| Application type: | First submission |
| Review commission: | CMO regio Arnhem-Nijmegen (Nijmegen) |
| Approved WMO Date: | 24-06-2024 |
| 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 | NL82292.091.22 |