

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

Published: 16-11-2022

Last updated: 04-07-2024

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

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 $^{166}\text{holmium}$ 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 \geq 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 $< 3.0 \times 10^9/l$ and/or platelet count $< 75 \times 10^9/l$.
6. Kidney failure: Creatine $> 165 \mu\text{mol/l}$ and/or eGFR $< 60 \text{ ml/min/1.73m}^2$
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 ^{166}Ho 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

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

Generic name: Intratumoural holmium-166 microspheres

Registration: Yes - CE outside intended use

Ethics review

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