Safety and feasibility of CT-guided percutaneous radionuclide therapy with the OncoSil* device in patients with non-progressive locally advanced pancreatic cancer (PANCOSIL): an open-label, single-arm phase 1-2 feasibility study

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To assess the safety and feasibility of percutaneous CT-or ultrasound-guided RNT using the Oncosil* device in patients with non-progressive LAPC after induction chemotherapy treatment.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Gastrointestinal neoplasms malignant and unspecified
Study type	Interventional

Summary

ID

NL-OMON54345

Source
ToetsingOnline

Brief title
PANCOSIL

Condition

- Gastrointestinal neoplasms malignant and unspecified
- Gastrointestinal therapeutic procedures

Synonym
Locally Advanced Pancreatic Cancer, Unresectable Pancreatic Cancer

Research involving
Human

Sponsors and support

Primary sponsor: Amsterdam UMC, locatie AMC
Source(s) of monetary or material Support: Oncosil Medical

Intervention

Keyword: Feasibility study, Locally advanced pancreatic cancer, Percutaneous, Radionuclide therapy

Outcome measures

Primary outcome

Safety and feasibility of percutaneous RNT using the Oncosil* device defined by

the percentage of complications CTCAE grade 3 or higher.

Secondary outcome

• Technical success, defined as adequate puncture of the tumour and injection

of the Oncosil* device, aiming at complete tumor ablation.

• Non-serious events, defined as events with a CTCAE grade <3.

• Duration of the overall procedure (defined as the total time in the radiology

suite).

• Overall survival: defined as the period of time between diagnosis and any

cause of death. Patients alive at last follow-up are censored.

• Progression-free survival: defined as the period of time between diagnosis

until progression in the original tumor location (disease progression defined

by the RECIST-criteria), new-onset lymph node-or distant organ involvement, as

discovered following complaints of the patient or on routine CT-scan

assessment.

• Difference in serum CA19-9 (area under the curve) during the first three

months post-RNT.

• Systemic immune response at several time points following treatment.

Study description

Background summary

Pancreatic ductal adenocarcinoma (i.e. pancreatic cancer) is one of the leading causes of cancer-related deaths worldwide. For the 40% of patients who present with non-metastatic locally advanced (unresectable) disease (i.e. LAPC), local ablative treatment modalities are being investigated to improve outcome. Internal-radiation therapy or radionuclide therapy (RNT) is one of these treatment options, which uses a radioactive agent inserted directly into the tumor to deliver a high-dose of internal radiation. Possible advantages of RNT over conventional external-beam radiation therapy include a higher dose of radiation to be delivered inside a tumor and sparing of the surrounding structures, resulting in a higher local tumor control rate and reduced morbidity. Promising outcomes of RNT for LAPC using the OncoSil* device are reported. Generally, this treatment modality is injected into the pancreatic tumor using endo-ultrasonography guidance (EUS). However, prospective series assessing the safety and feasibility of percutaneous RNT with the OncoSil* device using ultrasound or CT-guidance in LAPC are lacking.

Study objective

To assess the safety and feasibility of percutaneous CT-or ultrasound-guided RNT using the Oncosil* device in patients with non-progressive LAPC after induction chemotherapy treatment.

Study design

This is a prospective, single-arm, phase 1-2 feasibility study. This study follows the Transparent Reporting of Evaluations with Nonrandomized Designs (TREND) statement.

Intervention

Eligible patients will undergo percutaneous ultrasound or CT-guided OncoSil* injection. The first five procedures will be performed under general anaesthesia. The following five cases hereafter will be performed under sedation. Based on the treating physician*s judgment, the last five cases will

be performed under sedation or local analgesia. After OncoSil* treatment, patients will continue systemic chemotherapy and routine follow-up as is standard in clinical practice (i.e. consisting of three-monthly contrast-enhanced CT-scans and regular CA19-9 tumor marker assessment).

Study burden and risks

Currently, patients with LAPC are preferably treated with FOLFIRINOX or gemcitabine-nab-paclitaxel chemotherapy with palliative intent. Achieving local control with ablative therapies in stage III disease is expected to add 4-6 months to overall survival obtained with chemotherapy as determined by a recent systematic review and retrospective study of our research group. Furthermore, tumor load reduction may lead to pain reduction with improvement of quality of life. In this study, percutaneous RNT will be offered to a group of patients with LAPC. Early studies on LAPC treatment using OncoSil* combined with standard of care chemotherapy suggest the procedure to be feasible with an acceptable safety profile. Median overall survival, one-year survival and surgical resection rate were all significantly higher compared to the state of the art therapy.

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- Age >=18 years
- Locally advanced pancreatic cancer, defined by the DPCG consensus criteria as: arterial involvement >90* or venous involvement >270*.
- At least RECIST stable disease after a minimum two months of chemotherapy according to current clinical practice*
- Capable of providing written and oral informed consent
- Candidate for RNT, judged by a multidisciplinary tumor board
- WHO 0-2

* FOLFIRINOX for patients with WHO 0-1 performance status and gemcitabine-nab-paclitaxel for patients with > 1-2performance status.

Exclusion criteria

- Eligibility for resection
- Participation in other trials focussing on different ablative treatment modalities such as radiofrequency ablation or irreversible electroporation for LAPC
- Bleeding disorders which cannot be corrected with medication
- Inability/unwillingness to interrupt anticoagulation therapy
- ASA 3/4
- Pregnancy
- Metastatic pancreatic cancer
- Epilepsy episode(s) in the past six months
- Longest tumor diameter >70 mm or total target tumor volume >110 ml
- Presence of multiple collateral vessels surrounding or adjacent to the target tumor on radiologic imagining, prohibiting safe injection of the OncosilTM device
- Presence (or significant risk) of varices near the target tumor on radiologic imaging
- Recent clinically significant pancreatitis
- Previous administration of radiotherapy to the pancreas
- WHO > 2

Study design

Design

Study phase:	2
Study type:	Interventional
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	11-06-2023
Enrollment:	22
Type:	Actual

Medical products/devices used

Generic name:	Oncosil
Registration:	Yes - CE outside intended use

Ethics review

Approved WMO Date:	01-06-2023
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	26-05-2025
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	NL78596.000.22