PANcreatic Cancer lOcalized disease in frail or elderly patients unfit for both chemotherapy and surgery treated with Stereotactic Ablative Radiotherapy (PANCOSAR): a multicenter randomized controlled trial

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Ethical review	Approved WMO
Status	Recruiting
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON52822

Source
ToetsingOnline

Brief title
PANCOSAR

Condition

- Other condition
- Gastrointestinal neoplasms malignant and unspecified

Synonym
pancreatic cancer

Health condition

pancreascarcinoom

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum
Source(s) of monetary or material Support: AMR;collectebusfonds

Intervention

Keyword: Pancreatic cancer, radiotherapy, Stereotactic

Outcome measures

Primary outcome

The primary endpoint is to compare survival at six months in both study arms,

measured from the time of randomization.

Secondary outcome

- Quality of life (QoL) assessment using the European Organization for Research

and Treatment of Cancer (EORTC)

quality-of-life score questionnaires (QLQ-C30, version 3.0 and EORTC-PAN26)

assessed at baseline, 3-6-12 months

• Ca19.9: assessed at baseline, 3 and 6 months

• Toxicity will be scored using CTCAE criteria version 5.0: assessed at

baseline, day of last fraction, at 3 and 6 weeks (telephone consultation by

Radiation Oncologist), 3-6-12 months

• NRS pain score: assessed at baseline, 3-6-12 months

• WHO performance score: assessed at baseline, 3-6-12 months

Imaging after 3-6- and 12 months after treatment

Study description

Background summary

Pancreatic ductal adenocarcinoma (PC) is one of the most lethal cancers, its incidence increases with age. Many patients with localized (non-metastatic) PC have significant comorbidities, advanced age or a poor performance status which preclude chemotherapy and surgery. Because these patients are currently left untreated, it is desirable to find tolerable treatment options for these patients. A short course of high-dose precise radiation therapy i.e. stereotactic ablative body radiotherapy (SABR) may be feasible in these patients. Review of existing SABR literature for PC shows high local control rates, with relatively low toxicity and it was demonstrated to be feasible and well tolerated even in frail and elderly patients. It is, however, unknown whether SABR in the abovementioned poor prognosis subgroup of patients improves outcomes.

Study objective

The main goal of the current randomized study is to investigate if SABR may relieve tumor-related symptoms, improve the quality of life and potentially prolong survival in this frail patient group compared to best supportive care, which is the current treatment of choice in these patients.

Study design

This study is a multicentre randomized controlled trial according to the *cohort multiple randomized controlled trial (cmRCT)-design.

PACAP-participants have provided informed consent for being randomized in future unspecified cmRCTs. According to the cmRCT design, randomly selected patients will be informed about their random selection to receive the intervention within this trial, SABR. Furthermore, they will be informed that they are free to decide whether they want to adhere or deny this intervention for which they were randomly selected. In addition to spoken information, also written information will be provided to the patient. Patients have at least three days to read the information and consider their consent after which the (local) investigator or an authorized delegate will encounter the patient again for informed consent.
SABR will eventually be administered to patients within four weeks after

written consent.

Intervention

Five fractions of 8 Gy

Study burden and risks

Acute SABR-related toxicity may consist of fatigue, nausea, diarrhoea and temporary (increase of) local pain. Premedication can be prescribed to restrict such events. Subacute and late effects following high dose SABR can consist of gastrointestinal toxicity in the form of duodenal haemorrhage, strictures, ulceration or perforation, although literature findings suggest the incidence of these to be less than 5%.

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

• Pathology proven localised (non-metastasized) PC. Or when retrieving PA is difficult a multidisciplinary tumor board consensus on the diagnosis.
• Patients unfit for both surgery and systemic chemotherapy (i.e. KPS 50-70; WHO 2 or favourable WHO3) or patients who refuse surgery or chemotherapy. In case of prior treatment with chemotherapy: A maximum of two cycles of chemotherapy is allowed for inclusion. The interval between the last cycle of chemotherapy and the first fraction of radiation therapy should be at least six weeks. Additionally, in the case patient suffered from side effects of the chemotherapy these have to score equal or below 1 (CTCAE v.5.0) in before the first fraction of radiation therapy is delivered.
• Written informed consent

Exclusion criteria

• Age <18 years
• Administration of more than two cycles of chemotherapy
• Distant metastasis
• Imminent bowel obstruction
• Active bleeding
• Uncontrolled infection
• Contra-indications for MRI (only for VUmc and UMCU)
- pacemakers or implanted defibrillators, deep brain stimulators, cochlear implants. Patients who have a metallic foreign body in their eye, or who have an aneurysm clip in their brain, cannot have an MRI scan since the magnetic field may dislodge the metal
- Patients with severe claustrophobia not able to tolerate an MRI scan
- Patients with a non-MR-compatible (hip/knee/jaw) prosthesis

Study design

Design

Study phase:	2
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial

Masking:	Open (masking not used)

Primary purpose: Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	13-10-2020
Enrollment:	98
Type:	Actual

Ethics review

Approved WMO Date:	17-07-2020
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	14-09-2020
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	18-05-2022
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	10-10-2022
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	14-10-2024
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	NL72181.029.20