

# MR-guided adaptive stereotactic radiotherapy in localised pancreatic cancer

<b>Submission date</b>	<b>Recruitment status</b>	<input checked="" type="checkbox"/> Prospectively registered
12/08/2022	No longer recruiting	<input checked="" type="checkbox"/> Protocol
<b>Registration date</b>	<b>Overall study status</b>	<input checked="" type="checkbox"/> Statistical analysis plan
16/08/2022	Completed	<input checked="" type="checkbox"/> Results
<b>Last Edited</b>	<b>Condition category</b>	<input type="checkbox"/> Individual participant data
27/01/2026	Cancer	

## Plain English summary of protocol

<https://www.cancerresearchuk.org/about-cancer/find-a-clinical-trial/a-study-of-giving-radiotherapy-in-a-fewer-number-of-treatments-for-pancreatic-cancer-emerald>

## Background and study aims

An MR Linac combines two technologies – a magnetic resonance imaging (MRI) scanner and a conventional radiotherapy treatment machine (also known as a linear accelerator - Linac). Having radiotherapy (RT) on an MR Linac allows high-quality MR images to be taken daily before treatment and while the treatment is delivered with an associated adaptation of the radiotherapy treatment, called MR-guided adaptive RT. The optimal RT dose and schedule to treat pancreatic cancer are not known and doses have been limited by the need to keep the dose to normal surrounding tissues within accepted limits. Audit data has shown that when treatment is delivered on an MR Linac the tumour is targeted more effectively and normal tissues can be avoided. There is therefore the potential to safely deliver higher doses whilst keeping the dose to normal tissues within accepted limits. This study will evaluate whether increased RT doses and treatment over fewer days can be safely delivered to patients with pancreatic cancer on an MR Linac and whether this will improve the benefit of MR Linac treatment further. This study will also look at whether there are any changes in the tumours and normal tissues over the course of RT that can be seen on the MR images taken by the MR Linac, with the aim to find indicators from the imaging which may in the future be used to plan treatment more individually. The researchers will also collect blood samples to evaluate any changes in the immune response.

## Who can participate?

Patients aged 16 years or above scheduled to receive MRgRT for pancreatic cancer

## What does the study involve?

There are three phases to recruitment for this study: an initial safety run-in, a focussed recruitment phase, and an expansion phase. A recruitment pause may be implemented in any phase for any regimen if deemed necessary at any time. Participants receive either 5, 3 or 1-fraction MR-guided stereotactic radiotherapy over 1-3 weeks. The assigned choice is dependent on the order the patient is referred.

**What are the possible benefits and risks of participating?**

The participants will be having state-of-the-art- treatment over a very short time period. It is unknown whether the higher dose of RT or giving RT over a shorter period causes more side effects.

**Where is the study run from?**

The Churchill Hospital and the Genesis Care Clinic (UK)

**When is the study starting and how long is it expected to run for?**

July 2022 to January 2025

**Who is funding the study?**

MRC Institute for Radiation Oncology, Department of Oncology, University of Oxford, John Black Charitable Foundation, University of Oxford/GenesisCare Collaboration fund

**Who is the main contact?**

Lynda Swan, [octo-emerald@oncology.ox.ac.uk](mailto:octo-emerald@oncology.ox.ac.uk)

## Contact information

**Type(s)**

Public

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## Additional identifiers

### Clinical Trials Information System (CTIS)

Nil known

### Integrated Research Application System (IRAS)

279946

### ClinicalTrials.gov (NCT)

Nil known

### Protocol serial number

OCTRUM-330

### Central Portfolio Management System (CPMS)

52969

## Study information

### Scientific Title

Evaluation of hypofractionated adaptive radiotherapy using the MR Linac in localised pancreatic cancer

### Acronym

EMERALD - Pancreas

### Study objectives

To establish the safety of MR-guided hypofractionation stereotactic body radiotherapy (SBRT) in localised pancreatic cancer

### Ethics approval required

Old ethics approval format

### Ethics approval(s)

Approved 07/07/2022, West Midlands - Black Country Research Ethics Committee (The Old Chapel, Royal Standard Place, Nottingham, NG1 6FS, UK; +44 (0)207 1048010, +44 (0)207 1048141; blackcountry.rec@hra.nhs.uk), ref: 22/WM/0122

### Study design

Single-centre three-arm non-randomized interventional trial

### Primary study design

Interventional

### Study type(s)

Treatment

## **Health condition(s) or problem(s) studied**

Locally advanced pancreatic cancer

## **Interventions**

5, 3 or 1-fraction MR-guided stereotactic radiotherapy over 1-3 weeks. The assigned choice is dependent on the order the patient is referred.

## **Intervention Type**

Other

## **Primary outcome(s)**

Dose Limiting Toxicity (DLT) within 3 months from the start of magnetic resonance guided radiotherapy (MRgRT), defined as:

1. Grade 3 upper gastrointestinal bleeding
2. Gastro-intestinal fistula (any grade)
3. Grade 4 nausea/vomiting uncontrolled despite optimum anti-emetics
4. Grade 4 pancreatitis not stent-related
5. Vascular events (where these are not considered to be tumour related)

## **Key secondary outcome(s)**

1. Efficacy of MRgRT up to 24 months follow-up, assessed using:

1.1. Overall survival and progression-free survival

1.2. Freedom from local progression

1.3. Freedom from metastatic progression

2. Definitive resection rate for those undergoing surgery evaluated at surgery: R0/R1/R2 resection margin rates; rate of pathological complete response

3. Long-term toxicity rates (only those specifically related to SBRT):

3.1. All Grade 3+ toxicities to 12 weeks from the start of MRgRT

3.2. Any late GI adverse events (AE) > grade 2 (CTC v5) after 12 weeks from the start of MRgRT

4. Freedom from further line chemotherapy: time from the start of MRgRT to re-start of further chemotherapy, anytime from the start of MRgRT up to 24 months

## **Completion date**

31/01/2025

## **Eligibility**

### **Key inclusion criteria**

1. Participants must be fit and scheduled to receive MRgRT for pancreatic cancer. There are no specific restrictions on tumour size, number or interval from diagnosis
2. Localised pancreatic cancer, which may be
  - 2.1. Locally advanced and inoperable pancreatic cancer
  - 2.2. Inoperable on medical grounds
  - 2.3. Operable, but patient declines surgery
  - 2.4. Locally recurrent pancreatic cancer
3. Histologically proven pancreatic ductal adenocarcinoma or cytological proven pancreatic malignancy. Where histology/cytology is 'suspicious' MDT should confirm that it is appropriate to treat as malignancy
4. Male or Female, aged 16 years or above
5. Life expectancy of at least 6 months

6. ECOG performance status 0-1
7. Haematological and biochemical indices within defined ranges:
  - 7.1. Haemoglobin (Hb)  $\geq 8.0$  g/dL
  - 7.2. Platelet count  $\geq 50 \times 10^9/l$
  - 7.3. Neutrophils  $\geq 1.0 \times 10^9/l$
  - 7.4. Total bilirubin  $\leq 1.5 \times$  IULN
  - 7.5. AST(SGOT) or ALT(SGPT)  $\leq 3.0 \times$  IULN
8. Able (in the investigators' opinion) and willing to comply with all study requirements for the duration of the study
9. Willing and able to give informed consent

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Mixed

**Lower age limit**

16 years

**Upper age limit**

100 years

**Sex**

All

**Total final enrolment**

25

**Key exclusion criteria**

1. Patients with specific MRI exclusion criteria – metallic implants, shrapnel, claustrophobia or other expected intolerance of prolonged (up to 90 minutes) stay in an MRI scanner
2. Prior radiotherapy to the upper abdomen
3. Pregnant or breastfeeding women, or women of childbearing potential unless effective methods of contraception are used. Male patients who do not agree to use a condom during RT treatment and for 3 months after or who are not surgically sterile.
4. Distant metastatic disease or local disease that cannot be encompassed in the SBRT field

**Date of first enrolment**

24/08/2022

**Date of final enrolment**

09/11/2023

## Locations

**Countries of recruitment**

United Kingdom

England

**Study participating centre**

**Churchill Hospital**

Churchill Hospital

Old Road

Headington

Oxford

England

OX3 7LE

## Sponsor information

**Organisation**

University of Oxford

**ROR**

<https://ror.org/052gg0110>

## Funder(s)

**Funder type**

Hospital/treatment centre

**Funder Name**

GenesisCare

**Funder Name**

University of Oxford

**Funder Name**

MRC Institute for Radiation Oncology

**Funder Name**

John Black Charitable Foundation

**Alternative Name(s)**

The John Black Charitable Foundation, JBCF

**Funding Body Type**

Government organisation

**Funding Body Subtype**

Trusts, charities, foundations (both public and private)

**Location**

United Kingdom

## Results and Publications

**Individual participant data (IPD) sharing plan**

The data collected for the study, including individual participant data and a data dictionary defining each field in the set, will be made available to researchers on request to the study team and with appropriate reason, via [octo-enquiries@oncology.ox.ac.uk](mailto:octo-enquiries@oncology.ox.ac.uk). The shared data will be de-identified participant data and will be available for 3 years following the publication of the study. Data will be shared with investigator support, after approval of a proposal and with a signed data access agreement.

**IPD sharing plan summary**

Available on request

**Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Protocol article</a>		14/09/2023	15/09/2023	Yes	No
<a href="#">Basic results</a>		27/01/2026	27/01/2026	No	No
<a href="#">HRA research summary</a>			28/06/2023	No	No
<a href="#">Participant information sheet</a>		11/11/2025	11/11/2025	No	Yes
<a href="#">Protocol file</a>	version 3.0	25/09/2023	27/01/2026	No	No
<a href="#">Statistical Analysis Plan</a>	version 1.0	09/04/2024	27/01/2026	No	No
<a href="#">Study website</a>		11/11/2025	11/11/2025	No	Yes