

# MR-guided adaptive stereotactic radiotherapy in localised pancreatic cancer

<b>Submission date</b> 12/08/2022	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 16/08/2022	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 04/03/2025	<b>Condition category</b> Cancer	<input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> Record updated in last year

## 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

### **Study website**

<https://www.oncology.ox.ac.uk/clinical-trials/oncology-clinical-trials-office-octo/current-trials/emerald-pancreas>

## **Contact information**

### **Type(s)**

Public

### **Contact name**

Mrs Stephanie Levy

### **Contact details**

Oncology Clinical Trials Office (OCTO)  
Department of Oncology, The University of Oxford  
Old Road Campus Research Building  
Oxford  
United Kingdom  
OX3 7DQ  
+44 (0)1865 617084  
octo-emerald@oncology.ox.ac.uk

### **Type(s)**

Principal Investigator

### **Contact name**

Prof Somnath Mukherjee

### **Contact details**

MRC Oxford Institute for Radiation Oncology  
Gray Laboratories  
University of Oxford  
Old Road Campus Research Building

Roosevelt Drive  
Oxford  
United Kingdom  
OX3 7DQ  
+44 (0)1865 617415  
somnath.mukherjee@oncology.ox.ac.uk

## Additional identifiers

### EudraCT/CTIS number

Nil known

### IRAS number

279946

### ClinicalTrials.gov number

Nil known

### Secondary identifying numbers

OCTRU-330, IRAS 279946, CPMD 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

### Secondary study design

Non randomised study

## Study setting(s)

Hospital

## Study type(s)

Treatment

## Participant information sheet

<https://www.oncology.ox.ac.uk/clinical-trials/oncology-clinical-trials-office-octo/current-trials/emerald-pancreas>

## 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 measure

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)

## Secondary outcome measures

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

## Overall study start date

07/07/2022

## 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

## **Age group**

Adult

## **Lower age limit**

16 Years

## **Sex**

Both

## **Target number of participants**

Up to 60

## **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**

England

United Kingdom

**Study participating centre****Churchill Hospital**

Churchill Hospital

Old Road

Headington

Oxford

United Kingdom

OX3 7LE

## Sponsor information

**Organisation**

University of Oxford

**Sponsor details**

Research Governance, Ethics & Assurance (RGEA)

Boundary Brook House

Churchill Drive

Oxford

England

United Kingdom

OX3 7GB

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ctrng@admin.ox.ac.uk

**Sponsor type**

University/education

**Website**

<http://www.oucru.org/>

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**

### **Publication and dissemination plan**

Planned publication in a high-impact peer-reviewed journal

### **Intention to publish date**

31/12/2025

## 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="#">HRA research summary</a>			28/06/2023	No	No
<a href="#">Protocol article</a>		14/09/2023	15/09/2023	Yes	No