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A study of diffusing alpha-emitters radiation therapy for the treatment of different cancer types

Submission date 27/11/2025	**Recruitment status** Not yet recruiting	[X] Prospectively registered [_] Protocol
Registration date 05/08/2026	**Overall study status** Ongoing	[_] Statistical analysis plan [_] Results
Last Edited 05/08/2026	**Condition category** Cancer	[_] Individual participant data [X] Record updated in last year

Plain English summary of protocol

Background and study aims
The standard cancer treatments are surgery, radiotherapy, and chemotherapy. However, some cancers are difficult to treat, particularly when they have come back after previous treatment or are located close to important organs. This study aims to evaluate a new form of delivering radiotherapy called diffusing alpha-emitter radiation therapy (DaRT) for different types of cancer.
DaRT is a medical device that uses alpha radiation to treat cancer. In the DaRT device, Radium-224, a radioactive material, is coated onto the surface of small hollow metal tubes, called ‘sources’. The DaRT sources are inserted into tumours using special applicators. Once implanted, the radioactive particles detach from the surface of the source and release alpha radiation as they circulate inside the tumour.

Who can participate?
Patients aged 18 years or older with a biopsy-confirmed cancer that can be reached with the DaRT applicators

What does the study involve?
Participants will undergo screening assessments to confirm eligibility. If eligible, DaRT sources will be implanted into the tumour using special applicators. The DaRT sources will be removed after 14 days if this can be done easily; otherwise, they will be left in place permanently. Participants will be monitored regularly for treatment response and side effects. Follow-up includes clinical assessments, imaging scans, blood tests, and quality-of-life questionnaires for 6 months after treatment.

What are the possible benefits and risks of participating?
Previous studies suggest that DaRT may offer better tumour control with fewer serious side effects than standard treatments, although this cannot be guaranteed. Side effects are largely limited to the treated area and the implantation procedure and may include discomfort, pain, swelling, infection, bleeding, and inflammation of the treated area.

Where is the study run from?
Cambridge University Hospitals NHS Foundation Trust (UK)

When is the study starting and how long is it expected to run for?
March 2027 to March 2032

Who is funding the study?
The study is funded by Alpha Tau Ltd (Israel), the manufacturer of the DaRT device.

Who is the main contact?
Dr Li Tee Tan, litee.tan@nhs.net

Plain English summary under review with external organisation

Contact information

Type(s)
Principal investigator, Scientific

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Additional identifiers

Integrated Research Application System (IRAS)
357805

Central Portfolio Management System (CPMS)
68219

Study information

Scientific Title
A basket study of intra-tumoural diffusing alpha-emitters radiation therapy (DaRT) for the treatment of malignant tumours

Acronym
DaRT-Basket

Study objectives
Primary objective:
1. Assess the efficacy of DaRT treatment for different tumour types at different body locations with different treatment intent

Secondary objectives:
1. Assess the safety of DaRT treatment for different tumour types at different body locations
2. Assess the utility of DaRT implantation for different body locations when performed by different operators in different centres with different infrastructures

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 21/04/2026, South East Scotland Research Ethics Committee 02 (Mainpoint, 102 West Port, Edinburgh, EH3 9DN, United Kingdom; -; loth.sesres@nhs.scot), ref: 26/SS/0028

Primary study design
Interventional

Allocation
Non-randomized controlled trial

Masking
Open (masking not used)

Control
Active

Assignment
Multicenter pivotal device study

Purpose
Treatment

Study type(s)

Health condition(s) or problem(s) studied

Solid tumours

Interventions
This is a non-randomised pivotal study where all patients will be treated with the DaRT device. Patients will be allocated to one of three arms:
Arm 1: Patients with curable disease (new or recurrent, without metastatic disease)
Arm 2: Patients with recurrent disease within previously irradiated field (without metastatic disease)
Arm 3: Patients with incurable disease (including metastatic disease)

Initially, the study will focus on patients with the following tumour types – gynaecology, oral cavity, pancreas, prostate – as these are the sites in which there are ongoing DaRT studies worldwide and/or there is existing expertise in the study investigators with conventional brachytherapy and/or implantation techniques. It is anticipated that as the study investigators gain experience and confidence with the DaRT implantation techniques, treatment will be expanded to other tumour sites, including those in which there may not be ongoing DaRT studies elsewhere.
For each tumour type, patients may be allocated to any arm depending on their disease status. It is anticipated that Arm 1 will only include patients with tumour types for which conventional brachytherapy is a proven curative/salvage option, but access is limited in the UK due to lack of expertise, or patients who decline surgery in a desire for organ preservation.

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
DaRT

Primary outcome(s)
1. Response rate measured using tumour measurement and cross-sectional imaging at 6 weeks after device implantation

Key secondary outcome(s)
1. Response tate measured using tumour measurement and cross-sectional imaging at 3 months after after device implantation

2. Local control rate measured using tumour measurement and cross-sectional imaging at 3 months and 6 months after after device implantation

Completion date
01/03/2032

Eligibility

Key inclusion criteria
The participant must meet all the criteria to be included in the study:
1. Any biopsy-confirmed malignancy, new or recurrent, with or without metastatic disease

2. For patients with a known primary, repeat biopsy of recurrent/metastatic disease is desirable but not mandatory
3. Deemed likely to benefit from DaRT by treating tumour-specific multi-disciplinary team (MDT)
4. Measurable target according to RECIST v1.1
5. Target is technically amenable for coverage by DaRT sources
6. Patients with multiple target lesions are eligible if they meet all the inclusion criteria
7. Baseline imaging has been performed within 40 days of patient informed consent
8. Baseline imaging MUST also be within 60 days of DaRT insertion.
9. Last cycle of systemic treatment (chemotherapy or targeted therapy) will be given >30 days before DaRT insertion
10. For Arm 1 patients, no prior RT to the target lesion
11. For Arm 2 and Arm 3 patients, the last day of prior RT to the target lesion is >30 days before DaRT insertion
12. Age 18 years and over
13. ECOG performance status 0-2
14. Willing and able to give written informed consent to participate

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 Years

Upper age limit
120 Years

Sex
All

Total final enrolment
0

Key exclusion criteria
The presence of any of the following will preclude participant inclusion:
1. Involvement in other studies that may affect evaluation of response or toxicity of DaRT in the past 30 days
2. Significant comorbidity which may influence the response to or toxicity of DaRT treatment
3. Other concomitant malignancies requiring active treatment for progressive disease
4. Pregnancy or breastfeeding
5. Unwilling to use adequate contraception for the duration of the study if they or their partner (s) are of childbearing potential
6. Contraindications to DaRT implant (e.g. abnormal clotting in patients with target lesions at sites which have a significant risk from bleeding)

Date of first enrolment
02/03/2027

Date of final enrolment

01/03/2031

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Cambridge University Hospitals NHS Foundation Trust
Cambridge Biomedical Campus
Hills Road
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Study participating centre
Leeds Teaching Hospitals NHS Trust
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Study participating centre
Liverpool University Hospitals NHS Foundation Trust
Royal Liverpool University Hospital
Prescot Street
Liverpool
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L7 8XP

Sponsor information

Organisation
Cambridge University Hospitals NHS Foundation Trust

ROR
https://ror.org/04v54gj93

Funder(s)

Funder type

Funder Name
AlphaTau Medical

Alternative Name(s)
Alpha Tau Medical LTD., AlphaTau, Alpha Tau Medical

Funding Body Type
Private sector organisation

Funding Body Subtype
For-profit companies (industry)

Location
Israel

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available