ISRCTN13720905 https://doi.org/10.1186/ISRCTN13720905

Providing data so computer systems can help with the early identification of lung diseases, leading to more rapid treatment and better survival rates

Submission date
03/03/2022

Recruitment status
No longer recruiting

Registration date
07/04/2022

Overall study status
Completed

Last Edited
05/05/2022

Condition category
Cancer

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English Summary

https://www.cancerresearchuk.org/about-cancer/find-a-clinical-trial/a-study-to-develop-and-test-a-computer-programme-to-help-to-improve-the-diagnosis-of-lung-cancer#undefined (added 05/05/2022)

Background and study aims
In the UK, lung cancer is common with a very low 5-year survival rate as most patients are diagnosed at a late stage. Early detection on a CT scan when the cancers are small and seen as a nodule has been shown to improve survival.

DART will work with NHS England's ambitious Lung Cancer Screening programme using CT to collect clinical, CT and histology data for research aimed at improving lung cancer diagnosis and screening using artificial intelligence, AI.

If DART is successful, using artificial intelligence we will speed up the time to diagnose lung cancer whilst also identifying incidental harmless nodules on CT. DART aims to: remove the need for other investigations such as lung biopsies, making investigations safer and quicker; help pathologists diagnose lung cancer using; help patients by providing their doctors with more information on lung and heart function; improve patient selection for lung cancer screening.

DART aims to improve screening using AI, resulting in the avoidance of additional tests and biopsies which cause great patient anxiety, take time and are expensive.

DART will develop an AI algorithm for histology so that specimens from lung biopsies and resections can also be analysed in a similar fashion to CT scans.

Patients with lung cancer often have damaged lungs from smoking making surgery or radiation treatment unsafe. DART plans to develop an AI technique that can be used on all lung CT scans performed. As smoking can cause heart disease, patients screened for lung cancer often have heart disease. DART aims to use AI to see if we can identify this from their CT scans.

We will develop a specific risk model for Lung Cancer Screening selection, that outperforms published risk models that have been developed in academic institutions but are not used in clinical practice.

Who can participate?
To aid our research, it is important to gather data from as many people attending Lung Health Checks as possible. However, if you do not want your data included, now or at any time, please tell us using the contact details below

What does the study involve?
Computers will be to conduct additional analysis of scans and data from those attending lung health checks. It will not require any extra time or visits and will not interfere in any way with the standard health care.

Personal information will be kept private, but an NHS research laboratory will be able to link a patient's your data (health records, scans, biopsies and resections) accurately.

What are the possible benefits and risks of participating?
There are no health risks to participating. We will anonymise data by removing the code before it is used by researchers so there is no link back to patients, who will never be identified in research or publications.

There are no immediate benefits to participants, but participation will contribute towards:
• If found at an early stage, lung cancer is curable
• DART will develop an Artificial Intelligence software programme that is faster and accurate to assist doctors to interpret CT scans and detect cancer
• This will speed up the time to diagnosis and reduce the numbers of additional scans and biopsies that might be needed in future.
• As smoking can cause heart disease, patients screened for lung cancer often have heart disease, and we aim to use AI to see if we can identify this from their CT scans as well.

Where is the study run from?
The study is run from the University of Oxford (UK)

When is the study starting and how long is it expected to run for?
Data will be collected from lung health checks between 1st October 2020 and 31st July 2023

Who is funding the study?
The study is funded by UK Research and Innovation

Who is the main contact?
Prof Fergus Gleeson, Professor of Radiology, University of Oxford, fergus.gleeson@oncology.ox.ac.uk

Study website
https://dartlunghealth.co.uk

Contact information

Type(s)
Principal Investigator

Contact name
Prof Fergus Gleeson

ORCID ID
http://orcid.org/0000-0002-5121-3917

Contact details
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Old Road Campus
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Oxford
United Kingdom
OX3 7DQ
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fergus.gleeson@oncology.ox.ac.uk

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
301420

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
PID15885-A002-SP001, IRAS 301420, CPMS 51308

Study information

Scientific Title
The integration and analysis of Data using Artificial intelligence to impRove patient outcomes with Thoracic diseases

Acronym
DART

Study hypothesis
To develop an artificial intelligence prediction model for malignancy in pulmonary nodules detected on CT scans based on nodule characteristics including histology, and patient clinical risk profiles using machine deep learning models.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 24/02/2022, West Midlands - Black Country Research Ethics Committee (The Old Chapel, Royal Standard Place, Nottingham NG1 6FS; +44 (0)207 104 8010; blackcountry.rec@hra.nhs.uk), ref: 21/WM/0278, CAG 22/CAG/0010

Study design
Retrospective data collection

Primary study design
Other

Secondary study design

Study setting(s)
Community

Study type(s)
Other

Participant information sheet
https://dartlunghealth.co.uk/patients/ see Downloadable documents

Condition
Early diagnosis of lung cancer

Interventions
Data will be collected retrospectively from Lung Health Check centres, with patient consent. There will be no impact on patient care.

Intervention Type
Other

Primary outcome measure
1. Diagnosis of cancer measured by expert opinion using Targeted Lung Health Check spreadsheets and CT scans, collected from patients attending lung health checks first visit.
2. Diagnosis of cancer measured by AI model using Digital images collected from the CT scan.

Secondary outcome measures
1. Diagnosis of cancer determined by expert histology opinion from resection and biopsy specimens
2. Diagnosis of cancer determined by the AI model from the digitised resection and biopsy specimens

Overall study start date
01/10/2020

Overall study end date

31/07/2023

Eligibility

Participant inclusion criteria
Participants attending NHSE targeted lung health checks

Participant type(s)
Mixed

Age group
Adult

Sex
Both

Target number of participants
300,000

Participant exclusion criteria
Patients who request to not be included in any studies as part of the NHS opt out.

Recruitment start date
01/10/2020

Recruitment end date
31/07/2023

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
University of Oxford
Old Road Campus Research Building
Oxford
United Kingdom
OX3 7DQ

Study participating centre
Lancashire Teaching Hospitals NHS Foundation Trust
Preston Road
Chorley

United Kingdom
PR7 1PP

Study participating centre
Bradford Teaching Hospitals NHS Foundation Trust
Bradford
United Kingdom
BD9 6RJ

Study participating centre
Liverpool Heart and Chest Hospital NHS Foundation Trust
Thomas Drive
Liverpool
United Kingdom
L14 3PE

Study participating centre
Kettering General Hospital
Rothwell Road
Kettering
United Kingdom
NN16 8UZ

Study participating centre
University Hospitals Coventry and Warwickshire (UHCW) NHS Trust
Clifford Bridge Rd
Coventry
United Kingdom
CV2 2DX

Study participating centre
Doncaster and Bassetlaw Teaching Hospitals NHS Foundation Trust
Doncaster Royal Infirmary
Armthorpe Road
Doncaster
United Kingdom
DN2 5LT

Study participating centre

Hull University Teaching Hospitals NHS Trust (HUTH)
Anlaby Rd
Hull
United Kingdom
HU3 2JZ

Study participating centre
Luton and Dunstable University Hospital NHS Foundation Trust
Lewsey Rd
Luton
United Kingdom
LU4 0DZ

Study participating centre
Royal Brompton & Harefield Clinical Group, Part of Guy's and St Thomas' NHS Foundation Trust
Sydney Street
London
United Kingdom
SW3 6NP

Study participating centre
Salford Royal Foundation Trust
Stott Lane
Salford
United Kingdom
M6 8HD

Study participating centre
University Hospital of North Staffordshire
Princes Road
Stoke-on-trent
United Kingdom
ST4 7LN

Study participating centre
The Newcastle upon Tyne Hospitals NHS Foundation Trust
Freeman Hospital
Freeman Road
High Heaton

Newcastle upon Tyne
United Kingdom
NE7 7DN

Study participating centre
Gateshead Health NHS Foundation Trust Laboratory
Queen Elizabeth Hospital
Sherriff Hill
Gateshead
United Kingdom
NE9 6SX

Study participating centre
University Hospital Southampton NHS Foundation Trust
Southampton General Hospital
Tremona Road
Southampton
United Kingdom
SO16 6YD

Sponsor information

Organisation
Research Governance, Ethics & Assurance Team (RGEA), University of Oxford

Sponsor details
Joint Research Office
1st floor, Boundary Brook House
Churchill Drive
Headington
Oxford
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United Kingdom
OX3 7GB
-
ctrg@admin.ox.ac.uk

Sponsor type
University/education

Website
https://www.ukri.org/

ROR
https://ror.org/001aqnf71

Funder(s)

Funder type
Government

Funder Name
UK Research and Innovation

Alternative Name(s)
UKRI

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact, peer-reviewed journal

Intention to publish date
30/09/2023

Individual participant data (IPD) sharing plan
De-identified data will be shared with academic and industrial partners as approved by the CI

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No