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Clinical trial looking at different radiotherapy treatment schedules following chemotherapy for patients with non-small cell lung cancer

Submission date 25/07/2016	**Recruitment status** No longer recruiting	[X] Prospectively registered [X] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 27/07/2016	**Overall study status** Completed	
Last Edited 02/09/2024	**Condition category** Cancer	

Plain English summary of protocol
https://www.cancerresearchuk.org/about-cancer/find-a-clinical-trial/trial-find-best-way-giving-increased-dose-radiotherapy-treat-non-small-cell-lung-cancer-adscan

Contact information

Type(s)
Public

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Additional identifiers

EudraCT/CTIS number

IRAS number
190574

ClinicalTrials.gov number

Secondary identifying numbers
IRAS: 190574, ADSCaN2015

Study information

Scientific Title
ADSCaN: A Randomised Phase II trial of Accelerated, Dose escalated, Sequential Chemo-radiotherapy in Non small cell lung cancer

Acronym
ADSCaN

Study objectives
This trial will take 4 dose escalated accelerated sequential chemo-radiotherapy schedules into a randomized phase II comparison with a UK standard sequential chemo-radiotherapy using state of-the art radiotherapy. The overall aim of the trial is to identify which of the 4 experimental arms is the best schedule to take forward into a future randomised Phase III study.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 08/11/2016, West of Scotland REC 1 (Clinical Research & Development, West Glasgow Ambulatory Care Hospital, Dalnair Street, Glasgow, G3 8SW), REC ref: 16/WS/0165

Study design
Randomised phase II screening/"pick-the-winner" design

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
See study outputs table

Health condition(s) or problem(s) studied
Stage III Non-Small Cell Lung Cancer

Interventions

Minimisation incorporating a random factor will be used to allocate patients between treatment arms A:B:C:D:E so that an overall study ratio of 2:1:1:1:1 is achieved. Patients will only be randomised between the arms currently available at their hospital.

Arm A (Standard Arm): Patients will receive one radiotherapy session per day for 4 weeks (55Gy in 20 fractions over 26-28 days)

Arm B CHART-ED: Patients will receive 3 radiotherapy sessions per day for 2½ weeks (54Gy, 36 fractions, 12 days then 10.8Gy, 6 fractions (day 15-17)).

Arm C: IDEAL: Patients will receive one radiotherapy session per day for 5 weeks (Isotoxic radiotherapy 30 fractions, 5 weeks, prescribed dose 63-71Gy).

Arm D: I-START: Patients will receive one radiotherapy session per day for 4 weeks (Isotoxic radiotherapy 20 fractions, 4 weeks total dose of 55 – 65 Gy).

Arm E: Isotoxic IMRT: Patients will receive 2 sessions per day for 4 weeks (Isotoxic regime IMRT, individualised dose escalation to a maximum 79.2Gy in 1.8Gy over 4 weeks BD).

For all trial arms, once patients have completed treatment they will enter follow up and should be reviewed at months - 2, 3, 4, 6, 9, 12, 15, 18, 24 and 36 from randomisation. Thereafter annual visits should be performed until the end of the study period (June 2021). Follow up visits at more frequent intervals should be undertaken at the discretion of the participating Investigator.

Intervention Type
Other

Primary outcome measure
Progression free survival (PFS) is determined via RECIST reporting of scans performed at disease evaluation visits during follow-up at months 3, 6, 12, 18, 24 and 36 months

Secondary outcome measures
1. Overall survival (OS) is measured by collecting survival status at each follow up visit (months 2, 3, 4, 6, 9, 12, 15, 18, 21, 24, 36 and annually until the end of the study period (June 2021)). Cause of death and evidence for cause of death will be recorded by participating sites, and is collected from cancer centres, cancer registries and national databases.
2. Time to local-regional failure is determined via RECIST reporting of scans performed at disease evaluation visits during follow-up at months 3, 6, 12, 18, 24 and 36 months
3. Toxicity as assessed by NCI CTCAE v4.03 during treatment and during follow-up at months 3, 6, 12, 18, 24, 36 months and annually until end of study
4. Cost Effectiveness is based on quality adjusted life years calculated using resource-use data (delivery of radiotherapy, hospital inpatient/outpatient/high dependency days) and quality of life (EQ-5D) measured during treatment and follow-up (months 2, 3, 4, 6, 9, 12, 15, 18, 21, 24, 36 and annually until end of study)

Overall study start date
01/07/2015

Completion date
12/02/2022

Eligibility

Key inclusion criteria
1. Histologically or cytologically confirmed stage III NSCLC
2. Performance status (PS) – ECOG 0-2
Patients with PS 2 can only be included if the local investigator deems the general condition is explained by disease or the primary chemotherapy treatment
3. Inoperable disease, unsuitable for concurrent chemo-radiotherapy, in the opinion of the treating Oncologist
4. Patients who have had a complete response, partial response or stable disease on CT assessment after 2 cycles of platinum based chemotherapy
5. Willing and able to give written informed consent
6. Aged 16 or over
7. Adequate PFT results: FEV1 and/or KCO ≥ 40% of predicted

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
360

Key exclusion criteria
1. Previous or current malignant disease likely to interfere with the protocol treatment or comparisons
2. Medically unstable (unstable diabetes, uncontrolled arterial hypertension, infection, hypercalcaemia, ischaemic heart disease)
3. Connective tissue disorders (Scleroderma, Systemic Lupus Erythematosus)
4. Clinically significant interstitial lung disease
5. History of physical or psychiatric disorder that would prevent informed consent and compliance with protocol
6. Pregnant or lactating women
7. Any psychological, familial, sociological or geographical consideration potentially hampering compliance with the trial protocol and follow up schedule

Date of first enrolment
22/08/2017

Date of final enrolment
26/02/2021

Locations

Countries of recruitment
England

Northern Ireland

Scotland

United Kingdom

Wales

Study participating centre
Weston Park Hospital
Whitham Road
Sheffield
United Kingdom
S10 2SJ

Study participating centre
The Christie Hospital
Wilmslow Road
Manchester
United Kingdom
M20 4BX

Study participating centre
Velindre Cancer Centre
Velindre Road
Cardiff
United Kingdom
CF14 2TL

Study participating centre
Guys Hospital
Great Maze Pond
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SE1 9RT

Study participating centre
Clatterbridge Cancer Centre
Clatterbridge Road
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Study participating centre
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Study participating centre
Belfast City Hospital
95 Lisburn Road
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BT9 7AB

Study participating centre
Addenbrookes Hospital
Hills Road
Cambridge
United Kingdom
CB2 0QQ

Study participating centre
Bristol Haematology and Oncology Centre
Horfield Road
Bristol
United Kingdom
BS2 8ED

Study participating centre
Cheltenham General Hospital
Sandford Road
Cheltenham
United Kingdom
GL53 7AN

Study participating centre

The James Cook University Hospital
Marton Road
Middlesborough
United Kingdom
TS4 3BW

Study participating centre
Mount Vernon Cancer Centre, East and North Hertfordshire NHS Trust
Rickmansworth Road
Middlesex
United Kingdom
HA6 2RN

Study participating centre
North Wales Cancer Treatment Centre: Glan Clwyd Hospital, Ysbyty Gwyndd Hospital and Wrexham Maelor Hospital
United Kingdom
LL18 5UJ

Study participating centre
Northern Centre for Cancer Care, Freeman Hospital
Newcastle upon Tyne
United Kingdom
NE7 7DN

Study participating centre
Nottingham University Hospital
Hucknall road
Nottingham
United Kingdom
DG5 1PB

Study participating centre
Royal Marsden NHS Foundation Trust
Downs Road Sutton
London
United Kingdom
SM2 5PT

Study participating centre
South West Wales Cancer Hospital: Singleton Hospital
Swansea
United Kingdom
SA2 8QA

Study participating centre
University Hospital Southampton
Tremona Road
Southampton
United Kingdom
SO16 6YD

Sponsor information

Organisation
NHS Greater Glasgow & Clyde

Sponsor details
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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/05kdz4d87

Funder(s)

Funder type
Charity

Funder Name
Cancer Research UK

Alternative Name(s)

CR_UK, Cancer Research UK - London, CRUK

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
United Kingdom

Results and Publications

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

Intention to publish date
31/03/2023

Individual participant data (IPD) sharing plan
Not provided at time of registration

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	29/01/2019	30/01/2020	Yes	No
HRA research summary			28/06/2023	No	No
Other publications	Feasibility of isotoxic IMRT regimen	01/04/2021	02/09/2024	Yes	No
Participant information sheet	version 2.0	05/10/2016	02/09/2024	No	Yes