ISRCTN25458988 https://doi.org/10.1186/ISRCTN25458988

A study examining whether a new radiotherapy technique ("dysphagia optimised intensity modulated radiotherapy") will improve swallowing function after treatment in head and neck cancer patients

Submission date 23/12/2015	**Recruitment status** No longer recruiting	[X] Prospectively registered [X] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 23/12/2015	**Overall study status** Completed	
Last Edited 06/09/2024	**Condition category** Cancer	

Plain English Summary
https://www.cancerresearchuk.org/about-cancer/find-a-clinical-trial/a-study-looking-at-whether-changing-dose-radiotherapy-improves-swallowing-people-head-neck-cancer-dars

Study website
http://www.icr.ac.uk/our-research/our-research-centres/clinical-trials-and-statistics-unit/clinical-trials/dars

Contact information

Type(s)
Scientific

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Type(s)
Public

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
19934

Study information

Scientific Title
A phase III randomised multicentre study of dysphagia optimised intensity modulated radiotherapy (Do-IMRT) versus standard intensity modulated radiotherapy (S-IMRT) in head and neck cancer

Acronym
DARS

Study hypothesis
The aim of this study is to investigate whether dysphagia optimised intensity modulated radiotherapy (Do-IMRT) compared to standard IMRT (S-IMRT) improves post radiotherapy swallowing difficulties in patients with head and neck cancer.

Ethics approval required
Old ethics approval format

Ethics approval(s)
First MREC, 16/11/2015, ref: 15/LO/1464

Study design
Parallel group phase III multi-centre randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised parallel trial

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

Condition
Topic: Cancer; Subtopic: Head and Neck Cancer; Disease: Head and Neck

Interventions
Participants are randomly allocated to one of two groups:

Group 1: Participants receive dysphagia optimised intensity modulated radiotherapy (Do-IMRT)
Group 2: Participants receive standard intensity modulated radiotherapy (S-IMRT)

Radiotherapy doses will be the same in both groups; however, in Do-IMRT patients, the irradiation of the pharyngeal muscles will be reduced by delivering inverse planned IMRT identifying these as organs at risk. Patients in both treatment groups will receive 65 Gy in 30 fractions (2.167 Gy per fraction) to primary and nodal tumour (PTV_6500) and 54 Gy in 30 fractions (1.8 Gy per fraction) to remaining pharyngeal subsites and nodal areas at risk of harbouring microscopic disease (PTV_5400).

Unless contraindicated, patients will receive concomitant chemotherapy. Participants will be followed up after radiotherapy treatment at regular intervals for 24 months, and then annually for up to 5 years.

Intervention Type
Other

Primary outcome measure
Swallowing function, measured using the MD Anderson Dysphagia Inventory (MDADI) composite score at 12 months after treatment completion

Secondary outcome measures

1. Longitudinal pattern of patient-reported swallowing function, assessed by using the MDADI at baseline, 3, 6, 12, 18 and 24 months post treatment
2. Diet and eating habits, assessed by using the Performance Status Scale for Head and Neck Cancer (PSS-HN) at baseline, 3, 6, 12, 18 and 24 months post treatment
3. Swallowing function, assessed using the 100mL water swallow test and videofluoroscopic examination at baseline, 3, 6, 12, 18 and 24 months post treatment
4. Acute and late toxicity and use of feeding tube, assessed at baseline, weekly during radiotherapy at 1, 2, 3, 4 and 8 weeks post radiotherapy and then at 3, 6, 12, 18 and 24 months post treatment
5. Cancer-related outcomes, including resection rates, location and timing of loco-regional tumour recurrence and overall survival, assessed at follow-up visits 3, 6, 12, 18 and 24 months post treatment and then annually until 5 years post treatment

Overall study start date
18/12/2013

Overall study end date
31/07/2023

Eligibility

Participant inclusion criteria
Current inclusion criteria as of 29/08/2017:
1. Aged 18 years or above
2. Any patient undergoing radiotherapy for head and neck cancer in the oropharynx or hypopharynx. Patients with tumour at other sites (*1) where the radical radiotherapy dose is to be delivered to the pharyngeal constrictors may also be eligible
3. Stage T1-4, N0-3, M0 disease; this will be mostly histologically confirmed squamous cell carcinoma (SCC) but other histological types (*1) may be eligible
4. Radiotherapy with concomitant chemotherapy (unless conta -indicated) is the planned treatment
5. WHO performance status 0 or 1
6. Must be available to attend long term follow up
7. Adequate cognitive ability to complete the MDADI, UWQoL and PSSHN assessments
8. Written informed consent

*1 Sites are requested to confirm eligibility with ICR-CTSU prior to registration.

Previous inclusion criteria:
1. Aged 18 years or above
2. Any patient undergoing radiotherapy for head and neck cancer in the oropharynx or hypopharynx. Patients with tumour at other sites (*1) where the radical radiotherapy dose is to be delivered to the pharyngeal constrictors may also be eligible
3. Stage T1-4, N0-3, M0 disease; this will be mostly histologically confirmed squamous cell carcinoma (SCC) but other histological types (*2) may be eligible
4. Radiotherapy with concomitant chemotherapy (unless conta -indicated) is the planned treatment
5. Creatinine clearance (=50mL/min prior to starting chemotherapy) (*2)
6. WHO performance status 0 or 1

7. Must be available to attend long term follow up
8. Adequate cognitive ability to complete the MDADI, UWQoL and PSSHN assessments
9. Written informed consent

*1 Sites are requested to confirm eligibility with ICRCTSU prior to registration
*2 Not applicable for patients receiving radiotherapy only

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 102; UK Sample Size: 102

Total final enrolment
112

Participant exclusion criteria
Current exclusion criteria as of 29/08/2017:
1. Documented evidence of pre-existing swallowing dysfunction (not related to head and neck cancer)
2. Previous radiotherapy to the head and neck region
3. Posterior pharyngeal wall, post cricoid or retropharyngeal lymph node involvement
4. Lateralised tumours, requiring unilateral neck irradiation
5. Major head and neck surgery (excluding biopsies/tonsillectomy)
6. Current/previous tracheostomy placement
7. Previous or concurrent illness, which in the investigator's opinion would interfere with completion of therapy, trial assessments or follow up
8. Any invasive malignancy within previous 2 years (other than non melanomatous skin carcinoma or cervical carcinoma)

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7. Any invasive malignancy within previous 2 years (other than non melanomatous skin carcinoma or cervical carcinoma)

Recruitment start date
20/05/2016

Recruitment end date
27/04/2018

Locations

Countries of recruitment
England

Ireland

Northern Ireland

Scotland

Syria

United Kingdom

Wales

Study participating centre
Royal Marsden Hospital, Chelsea
Fulham Road
London
United Kingdom
SW3 6JJ

Study participating centre
Royal Marsden Hospital, Sutton
Downs Road
Sutton
United Kingdom
SM2 5PT

Study participating centre
Belfast City Centre Hospital
Lisburn Road
Belfast
United Kingdom
BT9 7AB

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

Study participating centre
Guy's and St Thomas' Hospital
Westminster Bridge Road
London
United Kingdom
SE1 7EH

Study participating centre
Weston Park Hospital
Whitham Road
Sheffield
United Kingdom
S5 7AU

Study participating centre
The Churchill Hospital, Oxford
Old Road
Headington
Oxford
Oxford
United Kingdom
OX3 7LE

Study participating centre
Royal Shrewsbury Hospital
Mytton Oak Road
Shrewsbury
United Kingdom
SY3 8XQ

Study participating centre
Worcester Royal Hospital
Charles Hastings Way

Worcester
Syria
WR5 1DD

Study participating centre
Norfolk & Norwich University Hospital
Colney Lane
Norwich
United Kingdom
NR4 7UY

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

Study participating centre
Gloucestershire Royal Hospital
Great Western Road
Gloucester
United Kingdom
GL1 3NN

Study participating centre
Royal United Hospitals Bath
Combe Park
Avon
United Kingdom
BA1 3NG

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

Study participating centre
Royal Devon & Exeter Hospital
Barrack Road
Exeter
United Kingdom
EX2 5DW

Study participating centre
Nottingham University Hospital
Derby Road
Nottingham
United Kingdom
NG7 2UH

Study participating centre
Western General Hospital
Crewe Road S
Edinburgh
United Kingdom
EH4 2XU

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

Study participating centre
Derriford Hospital, Plymouth
Derriford Road
Crownhill
Plymouth
United Kingdom
PL6 8DH

Study participating centre
Beatson West of Scotland Cancer Centre,
1053 Great Western Road

Glasgow
United Kingdom
G12 0YN

Study participating centre
Riagmore Hospital
Old Perth Road
Inverness
United Kingdom
IV2 3UJ

Study participating centre
Torbay Hospital
Lowes Bridge
Torquay
United Kingdom
TQ2 7AA

Study participating centre
St Luke's Hospital
St Luke's Radiation Oncology Network
Dublin
Ireland
-

Sponsor information

Organisation
Royal Marsden NHS Foundation Trust

Sponsor details
Fulham Road
London
London
England
United Kingdom
SW3 6JJ

Sponsor type
Hospital/treatment centre

Website
http://www.royalmarsden.nhs.uk/pages/home.aspx

ROR
https://ror.org/0008wzh48

Organisation
Cancer Trials Ireland

Sponsor details
Innovation House
Old Finglas Road
Dublin
Ireland
-

Sponsor type
Research organisation

Funder(s)

Funder type
Charity

Funder Name
Cancer Research UK

Alternative Name(s)
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 of trial results in a peer-reviewed journal.

Intention to publish date
31/12/2021

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	06/10/2016		Yes	No
Abstract results	results presented at ASCO	20/05/2020		No	No
HRA research summary			28/06/2023	No	No
Results article		06/07/2023	10/07/2023	Yes	No
Plain English results			06/09/2024	No	Yes