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 27/11/2025	**Condition category** Cancer	

Plain English summary of protocol
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

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
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 objectives
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

Study type(s)
Treatment

Health condition(s) or problem(s) studied
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.

Added 27/11/2025:
Additional Data Linkage Information:
Participants from this trial will also be included in the INTERACT project which will link to their data held by NHS England. For more information, please see the INTERACT website: https://www.icr.ac.uk/interact.

Intervention Type
Other

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

Key secondary outcome(s))
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

Completion date
31/07/2023

Eligibility

Key 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

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 years

Upper age limit
100 years

Sex

All

Total final enrolment
112

Key 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)

Date of first enrolment
20/05/2016

Date of final enrolment
27/04/2018

Locations

Countries of recruitment
United Kingdom

England

Northern Ireland

Scotland

Wales

Ireland

Syria

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

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

Study participating centre
Belfast City Centre Hospital
Lisburn Road
Belfast
Northern Ireland
BT9 7AB

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

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

Study participating centre

Weston Park Hospital
Whitham Road
Sheffield
England
S5 7AU

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

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

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

Study participating centre
Cheltenham General Hospital
Sandford Road
Cheltenham
England
GL53 7AN

Study participating centre
Gloucestershire Royal Hospital
Great Western Road

Gloucester
England
GL1 3NN

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

Study participating centre
Velindre Cancer Centre
Velindre Road
Cardiff
Wales
CF14 2TL

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

Study participating centre
Nottingham University Hospital
Derby Road
Nottingham
England
NG7 2UH

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

Study participating centre
University Hospital Southampton
Tremona Road
Southampton
England
SO16 6YD

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

Study participating centre
Beatson West of Scotland Cancer Centre,
1053 Great Western Road
Glasgow
Scotland
G12 0YN

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

Study participating centre
Torbay Hospital
Lowes Bridge
Torquay
England
TQ2 7AA

Study participating centre
Worcester Royal Hospital
Charles Hastings Way

Worcester
Syria
WR5 1DD

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

Sponsor information

Organisation
Royal Marsden NHS Foundation Trust

ROR
https://ror.org/0008wzh48

Organisation
Cancer Trials Ireland

Funder(s)

Funder type
Charity

Funder Name
Cancer Research UK

Alternative Name(s)
CR_UK, Cancer Research UK - London, Cancer Research UK (CRUK), CRUK

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location

United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		06/07/2023	10/07/2023	Yes	No
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
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Plain English results			06/09/2024	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes