

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	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 23/12/2015	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 27/11/2025	Condition category Cancer	<input type="checkbox"/> Individual participant data

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

Contact name

Mr Mark Sydenham

Contact details

DARS Trial Manager
ICR-Clinical Trials and Statistics Unit
Division of Clinical Studies
Institute of Cancer Research
Cotswold Road
Sutton
United Kingdom
SM2 4NG
+44 (0)208 722 4104
DARS-icrctsu@icr.ac.uk

Type(s)

Public

Contact name

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Contact details

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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 contra -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 contra -indicated) is the planned treatment
5. Creatinine clearance (≥ 50 mL/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)

Previous exclusion criteria:

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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
Scotland
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

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
Plain English results			06/09/2024	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes