

Clinical Implementation of PBT through UK Clinical Trials

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Proton Physics Research and Implementation Group (PPRIG) – 2023-11-10

Overview

- Role of RTTQA
- Role of RT QA in PBT trials
- Trial QA and Dosimetric Audit
- Current Trials
- Trials in set-up



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The Radiotherapy Trials QA (RTTQA) Group

The RTTQA Group is funded by the NIHR RTTPA THE NIHR National Institute for Health and Care Research

Design and implement QA programmes for NIHR CRN portfolio trials that include radiotherapy

Multi-professional Group across multiple NHS radiotherapy sites:

> Clinician Clinical scientist Radiographer Physicist Dosimetrist



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RTTQA Activity

- RT QA is not mandated for RT trials
- Central independent QA is recommended through the RT research community
- CRUK will ask if RT QA has been considered for a trial
- Safety, accuracy, consistency for multicentre trials across multiple anatomical sites
- Protocol compliance, meaningful endpoints



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Radiotherapy Trials Quality Assurance

Key QA Activity Areas





RTTQA Role in PBT Trials

- QA is essential for all RT trials and especially PBT
 - PBT novel in the UK
 - RCT trials help fill knowledge gap
- Ensures compliance with protocol
- Validates trial results
- QA is broken up into pre-trial and on-trial QA
 - Planning and delivery guidance
 - Via RT guidelines document
- How we assess plans
 - Assessment between proton centres or with external assessors
- Dosimetry audit work (e.g. IROC and NPL)

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Current Trials

Completed Recruitment:

- TORPEdO: Toxicity Reduction using Proton bEam therapy for Oropharyngeal cancer
 - 19 sites opened
 - 204 patients recruited, 135 PBT, 69 IMRT
 - Imaging and biology sub-studies recruiting
 - Comprehensive RT QA programme

Open Trials:

Radiotherapy Trials Quality Assuran

- Parable: Proton beam therapy in patients with breast cancer: evaluating early and late effects
 - 10 sites opened
 - 31 patients recruited, 15 PBT, 16 IMRT











- Assess whether IMPT compared with IMRT reduces treatment-related toxicities in patients with locally advanced oropharyngeal squamous cell carcinoma
- First UK PBT trial defined methodology and process for future UK trials
- Pre-trial QA
 - Contouring Benchmark (vs gold standard)
 - Unless streamlined by previous H&N trial QA
 - Planning benchmark case
 - Pre-contoured with target and OAR volumes
 - Dosimetry Audit
- On-trial QA
 - Prospective Contouring review
 - Prospective plan review for first IMRT and IMPT at each centre with external review
 - Timely retrospective plan review (ideally before mandated week 3 rescan)
- Needed to be sure we had optimal VMAT plans vs PBT or you haven't shown a real benefit



- Detailed planning guidance issued in the form of RT guidelines (for both PBT and VMAT)
- Outlining was prospectively reviewed for all cases (72 hour turnaround)
- At least the first IMRT and IMPT plans reviewed prospectively by international partner
- As this was a new site external retrospective review was done for all plans
- Dosimetry audit from IROC and MedAustron to validate site as these were the available audits at the start of the trial
- Subsequent NPL reference and H&N audit

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Report on TORPEdO Outlining T				
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- IROC Proton Head and Neck Phantom was used as part of the credentialling process for clinical trials
- Purpose of the phantom treatment experiment is confirm the dose distribution planned by an institution can be delivered correctly



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	Proton H&	Report of N Phantom	irradiation	
Date of Report Institution: Physicist: Radiation Machine: Insatment Planning S Date of Irradiation:	ystem: Va De	PT rian Eclipse-He cember 16, 202	los 11	
of procedure				
Chromic [™] Dosimetry precision of the TLD Summary of TLD	Media provided d is 3%, and the spa and film results	se profiles thro dal precision of	ugh the center of the film and de	of primary PTV. nshometer system is 1mm.
Location	ROC-H v. In	e 0	tena	Acceptable
PTV puperior	0.96	0.90	- 1.07	100
b. i.v. sourioi	0.97	0.90	- 1.92	100
Film Plane	Gamma kide	e 0	teria	Acceptable
Axial	94%		85%	Yes
Sagittal	\$3%	2	85%	Yes
rradiation results liete	d in the table abov	e do meet the a	riteria establish	ed by IROC in collaboration wi
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rradiation results liste e study groups. There rocess to enter pation Analysis by: Jessica Checked by:	d in the table abov fore, your institutio th in certain clinico Lowenstein and N	e do meet the i n has satisfied i trials that allo adia Hernandeo Sheph Direct	nteria establish the phantom in withe use of pro	ed by IROC in collaboration wir radiation component of the ton therapy.
Inaddition results lote a study groups. There is a study groups. There is a study groups. There is a study of the study of	d in the table above fore, your institution to certain clinica Lowerstein and N Lowerstein and N Lowerstein and N last this report ab plement to your made on the basi dage of all individe	e do meet the en des meet the en des setaided et taals that allo adia Homandeo data Homandeo Steph Borect build be consist i institution on is of this reposition concerne	Interior establish the phantom is the phantom is the phantom is the phantom is the phantom is the phantom is the phantom en Kry Ph.D. or, MD Anderso dered as a qu own commis y after you ha t a show. Such 1.	ed by ROC in collaboration of the on barray.
rendition result by: a fully groups. There incoses to enter patient analysis by: desica Checked by: Checked by: an provided to you be used, as a sup- anges should not be a with the full knowle	d in the table above fore, your institute to in certain clinica Lowernstein and N in this report ah plement to you se made by your made on the bar dge of all individ CARING	n do meet the in nas satisfied i halds that allow data Hernandez Steph Direct outid be consil r institution on is of this repo autis concerne NTEGRITT	Interestability the phontom in the phontom in the use of pro- ministry Ph.D. on Kry, Ph.D. on MD Anderson Served as a qui own commiss y after you be a face. Such 1. DISCOVIERY	ed by IROC in collaboration of the anabien component of the anabien programment of the methods of the second second second second second second and programment that changes the second se
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An Anthropomorphic Head and Neck Quality Assurance Phantom for Credentialing of Intensity-Modulated Proton Therapy

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The dosimetric precision of the TLD is 3%, and the spatial precision of the film and densitometer system is 1mm.

Summary of TLD and film results:					
Location	IROC-H v. Inst.	Criteria	Acceptable		
PTV Superior	0.96	0.93 - 1.07	Yes		
PTV Inferior	0.97	0.93 - 1.07	Yes		
Film Plane	Gamma Index*	Criteria	Acceptable		
Axial	94%	≥ 85%	Yes		
Sagittal	93%	≥ 85%	Yes		
*Percentage of points meeting gamma-index criteria of 7% and 4 mm					

The phantom irradiation results listed in the table above **do meet** the criteria established by IROC in collaboration with the cooperative study groups. Therefore, your institution **has satisfied** the phantom irradiation component of the credentialing process to enter patients in certain clinical trials that allow the use of proton therapy.



TORE - Audit











T T R PE O -Audit

- NPL Audit Tool- Proton head and NeCk Evaluation (PruDeNCE) Phantom- A phantom for end-to-end audits
 - Novel proton imaging and therapeutic proton tissue equivalent plastics
 - Tested at both UK PBT centres
 - Absolute dose measurements with either alanine pellets or ionisation chamber at equivalent points of measurement within tumour and spine region.
 - EBT3 film in coronal plane of the phantom
- Agreement between ionisation chamber and alanine to treatment planning calculations within 2% in the tumour region
- Film analysis showing 95% pass rate for 4%/3 mm global gamma analysis for both centres
- Dosimetry therefore validated in two ways



Author contact: hannah.cook@npl.co.uk

A new audit tool for proton therapy: Proton head and NeCk Evaulation (PruDeNCE) Phantom

H. Cook^{1,2}, N. Niemann³, C. Gillies⁴, V. Rompokos⁴, M. Lowe⁵, M. Hussein^{1,2}, C.H. Clark^{1,2,6,7}, R. Thomas^{2,8}, A. Nisbet¹, G. Royle¹, H. Palmans^{2,9}, A. Lourenço^{1,2}

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Department of Medical Physics are Biomedical Engineering, University Callegi Candon, WCIE & BT, U.K. Medical Relation Science, National Physics Laboration, Telditorium, Thrift J.K.W.U.K. "Barts Health Hrist Thrust, Chinical Physics Department, London, E.Y. BLL, U.K. Medical Physics Department, University Callegi Angels Marks Threaty, Octone, The Chinite Hrist Foundation Thust, MCIE & S.U.K. Chinite Medical Physics & Eliopreneira, Physics Department, London, E.Y. BLL, U.K. "Readomenty This Department, University Callegi Anton Beam Threaty, Octone, The Chinite Hrist Foundation Thust, MCIE & S.U.K. "Readomenty This Department, Linkensity Callegi Antone Threaty, VCIE & S.U.K. "Readomenty This Department, Januare Borger, UTRA), March Wanno Cancer Centre, HAB 30N, U.K. "Readomenty This Department, Devines, University of Sumy, Stag Hill, Guidhost, GUZ XXV, U.K. "Medical Physics Comp., Medivation In Threaty Centre, AT20 Withon, Linker, Husten, Hust, Threather, The Stage Medical Devines, University of Sumy, Stag Hill, Guidhost, GUZ XXV, U.K.



Courtesy of Hannah Cook- NPL





- Assess whether PBT can reduce mean heart dose without increasing shorter-term side effects, in patients with breast cancer who have increased risk of radiotherapy-induced heart toxicity.
- Second UK Trial- Refined methodology and process
- Pre-trial QA
 - Contouring Benchmark (vs gold standard), detailed contouring guidelines
 - Unless streamlined by a previous trial
 - Planning benchmarks
 - Two cases, one including SIB
 - Centres permitted to submit only case 1 if SIB technique under development
 - Prospective Contouring review for first three cases
 - Prospective plan review for first three IMAT and first five IMPT at each reviewed by peers and RTTQA
 - Timely retrospective plan review at periodic meetings by peers
- As trial was used to set up breast PBT in proton optimal VMAT treatment had to be the comparator



PARA // LE

- Detailed planning guidance issued in the form of RT guidelines (for both PBT and conventional)
- Outlining was prospectively reviewed for first three all cases (72 hour turnaround)
- At least the first three IMAT and first five IMPT plans prospectively peer reviewed
- Retrospective peer review is performed between UCLH and the Christie in MDT meetings
- Proton sites already had dosimetry audit from IROC so no further audit was required





Trials in Active Setup



Trial	Description	Phase	Status/Opening
APPPROACH Marking of Preters A. Patter Bulldhampt In Control Control of Control on A State Sta	Analysis of Proton vs. Photon Radiotherapy in Oligodendroglioma and Assessment of Cognitive Health	PH III	QA programme in progress. 7 centres ready to recruit. Q4 2023 intended opening
PROTIEUS	A Randomised Phase 2 Trial Comparing Proton versus Photon Based Neoadjuvant Chemoradiation, followed by Adjuvant Immunotherapy, in Oesophageal Cancer	PH II	QA programme ready to implement. Opening date TBC
PROTIS	PROTon beam therapy vs IMRT in Sinonasal cancer	PH III	QA programme ready to implement. Q2 2024 intended opening
HIT-Meso	Hemithoracic Irradiation with Proton Therapy in Malignant Pleural Mesothelioma	PH III	QA programme in setup. Opening date TBC



ECIP Studies



Trial	Description	Sample Size	Anticipated Start date
SUPERMAN	Selection of patients for proton beam radiotherapy for the management of abdominal neuroblastoma in children	100 (75 PBT/ 25 XRT)	Q1/2 2024
PRONTO	An Evaluative Commissioning Study for the Role of IMPT in the treatment of Malignant Parotid Tumours	100	Q1/2 2024
PARTNERS	An Evaluative Commissioning Study for the Role of IMPT in the treatment of Nasopharyngeal Cancers	100	Q1/2 2024
EMPHATIC	Evaluation of Combined Modality Proton and HepAtic Transplantation for Hilar Cholangiocarcinoma	25-30	Q1/2 2024

2 further adult ECIP studies are in development





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