

Quality assurance of the EORTC trial 22911. A phase III study of post-operative external radiotherapy in pathological stage T3N0 prostatic carcinoma: the dummy run.

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Abstract

Introduction: A dry run of a clinical trial (EORTC 22911) is presented in which 12 centres have participated. These are the centres which have contributed the largest number of patients to the trial.

Material and methods: Each participating centre received data from a suitable patient. Investigators were asked to plan and treat the patient according to the protocol guidelines and return the data for evaluation of compliance.

Results: The results show that compliance to the protocol guidelines was generally

good. There were a few minor deviations in the dose and fractionation schedule, in the volume reduction for the booster dose and in the dose prescription point. None of these deviations will affect the outcome of the study. The most important observation is the large inter-centre variation in target volumes.

Conclusions: The results of this study underlines the need for a strict definition of the target volume and the adoption of the ICRU 50 recommendations in future protocols.



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Keywords

Clinical trials; Prostate cancer; Quality assurance; Protocol compliance

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