

Protocolsynopsis

ReCare is a cohort within E²-RADIatE and focuses on cancer patients who are treated with high-dose re-irradiation. E²-RADIatE, which stands for the EORTC-ESTRO RADiotherapy InfrAstrucTure for Europe, is a prospective non-interventional non-therapeutic multi-cohort study or platform. It is a collaboration between the European Organization for Research and Treatment of Cancer (EORTC) and the European Society for Radiotherapy (ESTRO). The objective of E²-RADIatE is the collection of real-world data of cancer patients treated with radiotherapy, to support radiotherapy research and to provide evidence of the role of radiation oncology in a multidisciplinary approach. E²-RADIatE is open ended.

All study procedures, research governance, study ethics and other research considerations regarding ReCare will follow the EORTC 1811-E²-RADIatE protocol.

High-dose re-irradiation is defined according to the recent ESTRO EORTC consensus document (Andratschke, Willmann, Nieder et al. submitted). Re-irradiation is a new course of radiotherapy either to a previously irradiated volume (irrespective of concerns of toxicity) or where the cumulative dose raises concerns of toxicity. Thus, re-irradiation is an umbrella term for two different scenarios: 1) re-irradiation type I is any new course of radiotherapy that has geometrical overlap with the irradiated volume of previous courses; 2) re-irradiation type II is a new course with concerns of toxicity from the cumulative doses without overlap of irradiated volumes.

Two scenarios of repetitive radiotherapy are distinguished from re-irradiation: 1) Repeat organ irradiation is a new course of radiotherapy to a previously irradiated organ but without overlap of the irradiated volumes and without concerns for toxicity from cumulative doses; 2) Repeat irradiation is a new course of radiotherapy to an organ that has not been irradiated, without overlap of irradiated volumes, and without concerns for toxicity from cumulative doses. Repeat organ irradiation and repeat irradiation, as well as re-irradiation palliative non-therapeutic dose will be excluded from the ReCare cohort.