Chordomas are relatively rare lesions of the bones. About 30% occur in the sacroccocygeal region. Surgical resection is still the standard treatment. Due to the size, proximity to neurovascular structures and the complex anatomy of the pelvis, a complete resection with adequate safety margin is difficult to perform. A radical resection with safety margins often leads to the loss of bladder and rectal function as well as motoric/sensoric dysfunction. The recurrence rate after surgery alone is comparatively high, such that adjuvant radiation therapy is very important for improving local control rates. Proton therapy is still the international standard in the treatment of chordomas. High-LET beams such as carbon ions theoretically offer biologic advantages in slow-growing tumors. Data of a Japanese study of patients with unresectable sacral chordoma showed comparable high control rates after hypofractionated carbon ion therapy only. This clinical study is a prospective randomized, monocentric phase II trial. Patients with histologically confirmed sacroccocygeal chordoma will be randomized to either proton or carbon ion radiation therapy stratified regarding the clinical target volume. Target volume delineation will be carried out based on CT and MRI data. In each arm the PTV will receive
64 GyE in 16 fractions. The primary objective of this trial is safety and feasibility of hypofractionated irradiation in patients with sacrococcygeal chordoma using protons or carbon ions in raster scan technique for primary or additive treatment after R2 resection. The evaluation is therefore based on the proportion of treatments without Grade 3-5 toxicity (CTCAE, version 4.0) up to 12 months after treatment and/or discontinuation of the treatment for any reason as primary endpoint. Local-progression free survival, overall survival and quality of life will be analyzed as secondary endpoints. The aim of this study is to confirm the toxicity results of the Japanese data in raster scan technique and to compare it with the toxicity analysis of proton therapy given in the same fractionation. Using this data, a further randomized phase III trial is planned, comparing hypofractionated proton and carbon ion irradiation. ClinicalTrials.gov Identifier: NCT01811394.