Abstract

Study purpose: The DRAGON 1 trial aims to assess training, implementation, safety and feasibility of combined portal- and hepatic-vein embolization (PVE/HVE) to accelerate future liver remnant (FLR) hypertrophy in patients with borderline resectable colorectal cancer liver metastases.

Methods: The DRAGON 1 trial is a worldwide multicenter prospective single arm trial. The primary endpoint is a composite of the safety of PVE/HVE, 90-day mortality, and one year accrual monitoring of each participating center. Secondary endpoints include: feasibility of resection, the used PVE and HVE techniques, FLR-hypertrophy, liver function (subset of centers), overall survival, and disease-free survival. All complications after the PVE/HVE procedure are documented. Liver volumes will be measured at week 1 and if applicable at week 3 and 6 after PVE/HVE and follow-up visits will be held at 1, 3, 6, and 12 months after the resection.

Results: Not applicable.

Conclusion: DRAGON 1 is a prospective trial to assess the safety and feasibility of PVE/HVE. Participating study centers will be trained, and procedures standardized using Work Instructions (WI) to prepare for the DRAGON 2 randomized controlled trial. Outcomes should reveal the accrual potential of centers, safety profile of combined PVE/HVE and the effect of FLR-hypertrophy induction by PVE/HVE in patients with CRLM and a small FLR.

Trial registration: Clinicaltrials.gov: NCT04272931 (February 17, 2020). Toestingonline.nl: NL71535.068.19 (September 20, 2019).

Keywords: Colorectal cancer liver metastases (CRLM); Combined portal- and hepatic vein embolization (PVE/HVE); Future liver remnant (FLR); Hepatic vein embolization (HVE); Liver hypertrophy; Portal vein embolization (PVE).