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The effect of hyperthermic intraperitoneal chemotherapy (HIPEC) upon cytoreductive surgery (CRS) in gastric cancer (GC) with synchronous peritoneal metastasis (PM): A randomized multicentre phase III trial (GASTRIPEC-I-trial)

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Background

In patients (pts) with PM from GC, palliative chemotherapy (CTx) is the treatment of choice. CRS and HIPEC is still matter of debate, as the evidence is controversial. We conducted a randomized controlled multicentre trial to explore the impact of HIPEC after CRS on overall survival (OS). (Funding German Cancer Aid; ClinicalTrials.gov, number NCT02158988).

Methods

Pts with GC and histologically proven PM were randomized to arm CRS alone (with curative intent) (CRS-A) or arm CRS and HIPEC (CRS+H) with pre- and post-operative (op) CTx. CTx was defined as EOX; in case of HER-2 positivity it contained Cisplatin, Capecitabine and Trastuzumab. The HIPEC treatment consisted of Mitomycin C 15 mg/m^2 and Cisplatin 75 mg/m^2, in 5 litres of saline (60 min, 42 °C). Randomisation was stratified by centre, PCI, and HER2 status. The primary endpoint (EP) was OS, secondary EP progression and other distant metastasis free survival (PFS and MFS). Power analysis computed 180 pts. Analyses followed the intention to treat and time-to-event data by Fleming-Harrington test.

Results

Between 03/2014 and 06/2018 105 pts were randomized (52 pts to CRS+H and 53 pts to CRS-A) and recruitment was stopped due to slow recruitment. In total, 55 pts stopped treatment before CRS (disease progression or death). The median OS for both groups was 14.9 months (CRS-A 14.9 months (95% CI: 7.0-19.4) vs (CRS+H 14.9 months 95% CI: 8.7-17.7; p=0.1647). PFS was significantly improved from 3.5 months (95% CI 3.0-7.0) in the CRS-A group to 7.1 months (95% CI 3.7-10.5; p=0.0472) in the CRS+H group. The CRS+H group showed a better MFS 10.2 months (95% COI: 7.7-14.7) compared to 9.2 months (95% COI: 6.8-11.5; p=0.0286). Pts with grade > 3 adverse events during pre-op CTx and 30 post-op days were similar in both groups (46% and 43.6% in the CRS+H group, 62% and 38.1% in CRS-A group; p=0.160 and p=0.79, respectively).

Conclusions

The study showed no difference in OS in pts treated with CRS ± HIPEC. However, the PFS and MFS were significantly better in the CRS+H group. Therefore, further investigations seem worthwhile. Additional HIPEC did not compromise patient's safety.

Clinical trial identification

NCT02158988; EudraCT 2006-006088-22.

Legal entity responsible for the study

Charité - University of Berlin.

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Disclosure

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