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Systemic therapy, gastrectomy and CRS/HIPEC vs systemic therapy alone for gastric cancer with limited peritoneal dissemination: Results of the randomised PERISCOPE II trial

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Background

Synchronous peritoneal metastases (PM) are found in one third of gastric cancer (GC) patients. The prognosis of these patients is poor. The combination of gastrectomy and CRS/HIPEC is considered to be a promising treatment for GC patients with PM. However, its efficacy has not been compared to systemic therapy *alone* in a randomised controlled trial (RCT).

Methods

The PERISCOPE II study is a multicentre RCT. In the absence of disease progression after 3-4 cycles of systemic chemotherapy with/without immuno- or targeted therapy, patients with resectable cT3/T4a gastric adenocarcinoma with limited PM (PCI < 7) and/or tumour-positive peritoneal cytology were randomly assigned (1:1) to the standard arm (arm S; continuation of systemic therapy) or the experimental arm (arm E; gastrectomy and CRS/HIPEC). The perfusion protocol included oxaliplatin (460mg/m^2) at 41°C for 30 min and docetaxel (50mg/m^2) at 37°C for 90 min. The primary endpoint was overall survival (OS). Secondary endpoints were progression-free survival, treatment-related toxicity and quality of life.

Results

Between 2017 and 2024, 102 patients were included (51 in both arms). The trial was closed prematurely due to a commissioned interim analysis. Data analysis at a minimum follow-up of 6 months showed a median OS of 15.7 months (95% CI: 11.2 – 25.5) in arm E, compared to 16.3 months (95% CI: 14.1 – 21.9) in arm S; HR 1.11 (95% CI: 0.7 – 1.77); p = 0.67. In arm E, 13 patients did not undergo CRS/HIPEC due to disease progression or patient refusal. Seven patients in arm S underwent CRS/HIPEC abroad, outside the study protocol. The per protocol analysis showed a median OS of 17.3 months (95% CI: 13.7 – 37.7) in arm E and 15.6 months (95% CI: 13 – 21.1) in arm S; HR: 0.66 (95% CI: 0.38 – 1.12); p = 0.12. There were 41 serious adverse events (SAEs) in 21 patients (44%) in arm E compared to 5 SAEs in 4 patients (8%) in arm S. At 100 days after randomisation, 3 treatment-related deaths had occurred, all in arm E.

Conclusions

In the PERISCOPE II study, gastrectomy and CRS/HIPEC provided no survival benefit in patients with gastric cancer and limited PM compared to systemic therapy alone. Gastrectomy and CRS/HIPEC resulted in an increased rate of SAEs.

Clinical trial identification

NCT03348150; registration date November 2017; first enrollment November 2017; end date September 2024.

Legal entity responsible for the study

Johanna van Sandick.

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Disclosure

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