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**Fecal microbiota capsules from healthy donors to improve treatment response in patients with locally advanced, resectable gastric or gastro-esophageal junction adenocarcinoma: A randomized, placebo-controlled phase II study (CAPGO)**T. van den Ende<sup>1</sup>, S. Siegerink<sup>1</sup>, K. Wortelboer<sup>2</sup>, N.C. De Clercq<sup>1</sup>, N.C. van Grieken<sup>3</sup>, T.D. de Gruijijl<sup>1</sup>, M.F. Bijlsma<sup>4</sup>, M. Nieuwdorp<sup>2</sup>, H.W.M. van Laarhoven<sup>1</sup>

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**Background**

For patients with resectable gastroesophageal cancer (GEC) perioperative chemotherapy with fluorouracil, leucovorin, oxaliplatin and docetaxel (FLOT) is one of the main modalities. However, treatment with FLOT can lead to gastro-intestinal toxicity and gut dysbiosis. Moreover, disease relapse is observed in approximately 50% of patients. Thus, there is a need to improve this established protocol. The gut microbiota has gained traction in recent years as a new target for improving immuno and chemotherapy response. Clinical and pre-clinical studies have shown associations between different gut bacteria and their produced metabolites and immune responses. In the previous TRANSIT study we showed improved disease control rate in metastatic GEC patients who received an allogenic faecal microbiota transplantation (FMT). In the CAPGO study we will investigate if FMT can be performed in an earlier disease stage and by administration via lyophilized faecal microbiota capsules (LFMC). The aim of this study is to reduce toxicity, improve treatment response and survival through FMT in resectable GEC.

**Trial design**

CAPGO is a double-blind phase II study recruiting patients with resectable GEC eligible for treatment with FLOT. Patients are randomized (1:1) between LFMCs or placebo capsules. To enrich for a healthy gut microbiota allogenic donors need to be athletic and have a lean body mass above 80% measured by bioelectrical impedance analysis. Patients receive standard of care FLOT, four preoperative and four postoperative cycles. Additionally, one LFMC or placebo capsule is given once a day for seven days before each preoperative cycle. Primary outcome of the study is the percentage of patients with a tumour regression grade of 1-2. Secondary outcomes are toxicity, quality of life, recurrence and survival. Exploratory analyses on changes in gut and tumour microbiota composition, plasma metabolites, cytokines and peripheral immune cells will be performed on material collected at baseline, week 4 and 12. Recruitment commenced in June 2024, five donors and three out of 44 patients have been enrolled.

**Clinical trial identification**

Dutch Medical Research Overview ID: NL-OMON56807.

**Legal entity responsible for the study**

Amsterdam University Medical Center.

**Funding**

Cancer Center Amsterdam.

**Disclosure**

H.W.M. van Laarhoven: Financial Interests, Institutional, Invited Speaker: Astellas, BMS, JAAP, Medtlaks, Travel Congress Management BV, AstraZeneca, Servier; Financial Interests, Institutional, Advisory Board: Amphera, Astellas, BeiGene, Daiichi, Servier; Financial Interests, Institutional, Other, Advices on protocol development: Myeloid; Financial Interests, Institutional, Other, Selection of articles for Framingham: Framingham; Financial Interests, Personal, Member of Board of Directors: IKNL; Financial Interests, Institutional, Research Grant, LyRICX study: Servier; Financial Interests, Institutional, Research Grant, TAPESTRY study: Merck; Financial Interests, Institutional, Research Grant, AUSPICIOUS study: Incyte; Financial Interests, Institutional, Research Grant, LOAD study: Orca; Financial Interests, Institutional, Coordinating PI: Auristone; Financial Interests, Institutional, Steering Committee Member, DESTINY-GASTRIC03: AstraZeneca; Financial Interests, Institutional, Funding: Amgen; Financial Interests, Institutional, Research Grant: BMS; Non-Financial Interests, Leadership Role, Chair upper GI Faculty: ESMO; Non-Financial Interests, Institutional, Product Samples, For all clinical study mentioned, study medication is

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