

To the press

Study shows efficacy of dual-HER2 targeted therapy for patients with HER2-positive colorectal cancer
Investigator-initiated trial based on GI-SCREEN-Japan/GOZILA study may lead to the world's first effective treatment for HER2-positive colorectal cancer

November 12, 2021

National Cancer Center Japan

Japan Agency for Medical Research and Development

[Highlights]

- National Cancer Center Hospital East (Director: Atsushi Ohtsu), the National Cancer Center (President: Hitoshi Nakagama) conducted an investigator-initiated clinical trial (TRIUMPH study, EPOC1602) to evaluate the efficacy and safety of the combination of pertuzumab and trastuzumab, an anti-HER2 antibody therapy, in patients with HER2-positive colorectal cancer confirmed by tumor tissue analysis or liquid biopsy.
- This trial showed that a tumor response was achieved in approximately 30% of patients, confirming that the results exceeded the predetermined efficacy criteria.
- The results of the TRIUMPH study were also compared with those of patients with HER2-positive colorectal cancer who met the same criteria in the SCRUM-Japan Registry and suggested that the combination therapy may have superior efficacy compared with conventionally used anti-cancer treatment. The TRIUMPH study was the first clinical trial in the world to show the efficacy of the combination therapy in patients with HER2-positive colorectal cancer prospectively confirmed by liquid biopsy.
- Longitudinal liquid biopsies revealed several characteristics that indicate a high likelihood of efficacy, suggesting that repeated liquid biopsies may be useful in predicting treatment efficacy. The results have been published online in "*Nature Medicine*" on 12 November 2021, Japan time.

[Prospects]

The results of this trial are expected to lead to the world's first effective treatment for patients with HER2-positive colorectal cancer patients. In addition, liquid biopsy may be utilized for the selection of therapeutic drugs for colorectal cancer patients, prediction of efficacy, and discovery of resistance factors.

[Publication]

Journal name: *Nature Medicine*

Title: Circulating tumor DNA-guided treatment with pertuzumab plus trastuzumab for metastatic colorectal cancer with HER2 (ERBB2) amplification: the TRIUMPH phase 2 Trial (EPOC1602)

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[Support]

Japan Agency for Medical Research and Development (AMED)

- Project Promoting Clinical Trials for Development of New Drugs
"Investigator initiated trial in HER2-positive unresectable and recurrent colorectal cancer utilizing the Nation-wide genome screening consortium (SCRUM-Japan) patient registry" (Principal Investigator: Takayuki Yoshino)(JP20lk0201054)
- Practical Research for Innovative Cancer Control
"Creation of Comprehensive Catalog on Clonal Evolution of Cancer Genome Alteration in Metastatic Colorectal Cancer Utilizing Circulating Tumor DNA Analysis" (Principal Investigator: Yoshiaki Nakamura)(JP20ck0106445)
- Project Promoting Clinical Trials for Development of New Drugs
"Constructing a cancer registry based on the nation-wide genome screening project (SCRUM-Japan) for new oncology agent development" (Principal Investigator: Atsushi Ohtsu) (JP18lk0201056)

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