



特定機能病院
愛知県がんセンター
Aichi Cancer Center

Revolutionizing Cancer Treatment: Launching Japan's Premier Pragmatic Clinical Trial for Colorectal Cancer to Fast-Track Therapeutic Innovation and Streamline Clinical Trials.

Highlights

- The Aichi Cancer Center has launched a groundbreaking randomized Phase III trial, named PRABITAS (jRCTs041230120), to compare conventional and biweekly regimens of trifluridine/tipiracil plus bevacizumab combination therapy in treating colorectal cancer. This trial is set to be the largest of its kind in Japan, involving approximately 250 medical institutions. Over the course of a year, it is anticipated that 890 patients will participate.
 - This trial marks a significant milestone as it adopts a “pragmatic” clinical trial method, a first in the field of cancer treatment in Japan. Pragmatic clinical trials are conducted under conditions closely mirroring real-world medical settings and involve a diverse range of medical institutions and patients. This approach aims to yield results that can be directly applied in everyday clinical practice, helping to inform treatment decisions.
 - One of the key benefits of this trial is the potential to establish a new standard of treatment that is less burdensome in terms of side effects and more convenient for patients. Moreover, the implementation of pragmatic clinical trials is expected to demonstrate a method of clinical research that is less taxing for both patients and healthcare providers, enhancing the efficiency of clinical trials. This, in turn, could significantly accelerate the development of new treatments. By conducting this trial, the Aichi Cancer Center is at the forefront of innovative cancer research, with the potential to revolutionize treatment protocols and improve patient care in cancer therapy.
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Innovations in Colorectal Cancer Treatment: Trifluridine/Tipiracil Plus Bevacizumab Therapy

Trifluridine/tipiracil plus bevacizumab therapy, a significant advancement in colorectal cancer treatment, is administered in a 28-day cycle as per conventional protocol. This involves taking the anti-cancer medication twice daily for five days, followed by a two-day break, and then repeating this cycle once before a two-week drug holiday. Widely adopted worldwide as a standard treatment for colorectal cancer, this therapy commonly causes side effects like leukopenia and neutropenia. Consequently, a more patient-friendly biweekly regimen has been proposed, entailing medication for five days followed by a nine-day break in a 14-day cycle. Early small-scale clinical trials have reported this approach to reduce side effects. However, the efficacy and safety of this biweekly method still require thorough validation through randomized controlled trials (RCTs) by randomly assigning participants to different treatment groups and comparing both regimens.

A New Approach in Clinical Trials: Pragmatic Randomized Clinical Trials

Traditional RCTs in cancer treatment, while scientifically rigorous under specific conditions, often don't translate seamlessly into everyday clinical practice, posing a significant challenge. Pragmatic clinical trials address this issue by minimizing barriers to participation, such as stringent eligibility criteria and treatment protocols, thereby closely mirroring real-world medical settings. These trials involve diverse medical institutions and patients, allowing the results to be directly applicable in determining treatment strategies in routine clinical practice. Furthermore, they simplify data collection from participating medical institutions, significantly reducing the human and financial resources needed to conduct the trials. This approach promises faster trial completion, cost reduction in development, and more efficient progress in treatment development for pharmaceutical companies and healthcare professionals.

Aichi Cancer Center Launches Landmark PRABITAS Trial in Colorectal Cancer

The Aichi Cancer Center's Department of Clinical Oncology, led by Director Kei Muro and Chief Physician Hiroya Taniguchi, has initiated a multi-institutional Phase III trial (PRABITAS) comparing the conventional and biweekly regimens of trifluridine/tipiracil plus bevacizumab combination therapy in patients with unresectable colorectal cancer with prior treatment history. The primary objective of this trial is to verify the non-inferiority of the increasingly popular biweekly regimen compared to the conventional method in terms of efficacy.

This trial employs the method of pragmatic randomized clinical trials, significantly reducing the number of eligibility criteria compared to traditional trials. While the medication regimens are randomly assigned, subsequent treatments and examinations are conducted as in routine clinical practice. Involving about 250 medical institutions nationwide, the trial aims to enroll 890 patients over a year, making it the largest Phase III trial for unresectable colorectal cancer in Japan. Furthermore, this represents Japan's first foray into pragmatic clinical trials in the field of cancer.

The trial's operations are managed by the Center's Clinical Trial Department, led by Director Masashi Ando.

A pragmatic, randomized phase III trial of bi-weekly vs conventional schedule of FTD/TPI plus bevacizumab for metastatic colorectal cancer (PRABITAS)

Study ID: jRCTs041230120

Patients

- Histologically confirmed mCRC
- Known RAS status
- ECOG PS 0-2
- A history of chemotherapy
- No history of receiving FTD/TPI



Conventional schedule (28-day cycle)

FTD/TPI
Day 1-5, Day 8-12
Bevacizumab:
Day 1, Day 15

Bi-weekly schedule (14-day cycle)

FTD/TPI
Day 1-5, Day 8-12
Bevacizumab:
Day 1, Day 15

Sponsor	Aichi Cancer Center Hospital
Enrollment	890 patients (Estimated)
Participation	250 institutions
Study start	December 2023
Study end	December 2026

Future Prospects: A New Chapter in Cancer Clinical Trials at Aichi Cancer Center

As the Aichi Cancer Center continues its groundbreaking work in cancer clinical trials, the focus now shifts to the prospects shaped by the ongoing PRABITAS trial. This trial, aiming to establish the efficacy and safety of the biweekly regimen for colorectal cancer treatment, holds the potential to introduce a new standard of care with reduced side effects and greater convenience.

The successful validation of the biweekly regimen would not only offer a more patient-friendly treatment option but also pave the way for more efficient therapeutic development. The insights gained from the pragmatic clinical trial approach could significantly reduce the burden on patients and healthcare providers, fostering the creation of more patient-centric cancer clinical trials. This, in turn, is expected to accelerate the development of novel treatments.

The Aichi Cancer Center has been at the forefront of modernizing clinical trials, consistently working towards developing new models of clinical studies and trials. In a pioneering move last year, the center also launched Japan's first entirely decentralized clinical trial (cancer-c.pref.aichi.jp/uploaded/attachment/1206.pdf). With the initiation of Japan's first pragmatic clinical trial, the center is set to contribute even more significantly to the advancement of cancer research and care.

This innovative trial is seen as an important step towards the future of cancer clinical trials, bringing hope to patients and the medical community alike. The Aichi Cancer Center remains committed to playing a vital role in this evolution, continually pushing the boundaries of what is

possible in cancer treatment and research.

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