

# NCCH2006/MK010 Trial (FORTUNE Trial)

NCT04962867

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<b>Status</b>	RECRUITING
<b>Phase</b>	Phase 2
<b>Sponsor</b>	National Cancer Center, Japan
<b>Enrollment</b>	75 participants

## Key Eligibility Criteria

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### Inclusion (28)

- Participants with histologically or cytologically confirmed metastatic, unresectable, or recurrent solid tumor who agree to provide an archival tumor sample, a residual biopsy sample, or a fresh tumor biopsy sample
- Ineffective to or intolerant to initial treatment, or for which standard treatment is no longer available
- Participants with an FGFR gene alteration detected by NGS panel, who fall under one of the categories of groups A to C and E defined as below
- Group A: FGFR1-3 fusion
- Group B and E: FGFR1-3 specific activating mutations as below;  
... and 23 more (see full listing online)

### Exclusion (9)

- Participants with brain, subdural or leptomeningeal metastases
- Participants with primary CNS tumor located in either cerebellum, brainstem, spinal cord, pituitary gland, optic nerve or olfactory nerve
- Positive for either human immunodeficiency virus (HIV) antibody, HBs antigen, or HCV antibody (patients with positive HCV antibody but no detectable HCV-RNA are not excluded)
- Negative for HBs antigen, but positive for HBs antibody or HBc antibody, and also positive for HBV-DNA quantification (not excluded if HBV-DNA is below detection sensitivity)
- Child-Pugh score B or C  
... and 4 more (see full listing online)

## Locations (7 total)

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National Cancer Center Hospital, Chuo-ku, Tokyo, Japan, Japan  
Kanagawa Cancer Center, Yokohama, Kanagawa, Japan  
Tohoku University Hospital, Aoba-ku, Sendai, Miyagi, Japan  
... and 4 more locations

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<https://clinicaltrials.gov/study/NCT04962867>

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