

Enrolling in late Summer 2020

NRG-CC005 “FORTE”

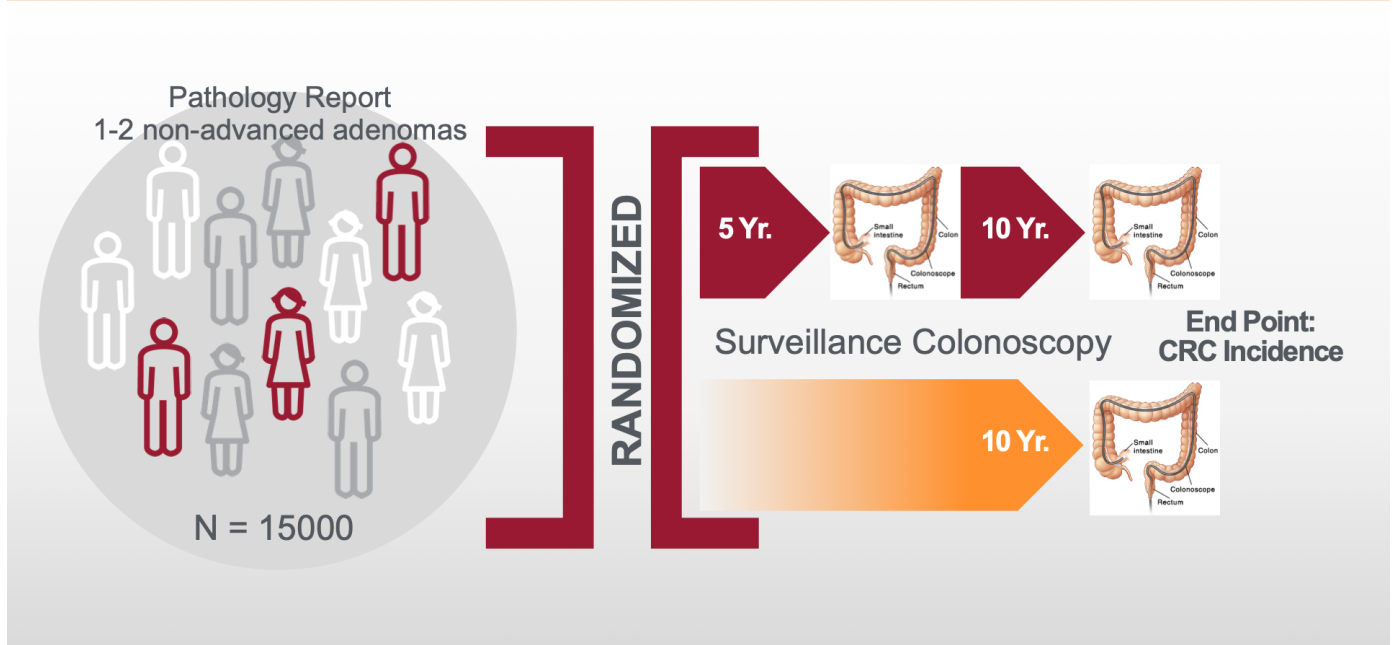
Five or Ten Year Colonoscopy for 1-2 Non-Advanced Adenomatous Polyps

Protocol Chair:
Assistant Protocol Chair:
Chief Scientific Officer:

Robert E. Schoen, MD, MPH
Jeffrey M. Dueker, MD, MPH
Douglas Corley, MD, PHD

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A COLORECTAL CANCER PREVENTION TRIAL



Study Overview

FORTE is a colorectal cancer prevention study to determine whether people with 1 or 2 benign adenomatous polyps should have a repeat colonoscopy exam at 10 years or at 5 **and at** 10 years. The best timing for a repeat colonoscopy is not known. Do participants need an exam at 5 years? That is the question that needs answering. FORTE will randomize 15,000 participants. FORTE will measure and compare the colorectal cancer incidence rates in the two groups and see if the cancer rates are similar. If the cancer rates are non-inferior to each other, then in the future, a 5-year follow-up surveillance colonoscopy exam may not be needed.

For more information about the NRG FORTE trial, please visit the CTSU Web site at www.ctsu.org
For eligibility and clinical questions about NRG CC005 contact the NRG Clinical Coordinating Department (CCD) at 1-800-477-7227 or ccdPGH@nrgoncology.org

Why FORTE?

Observational studies suggest that the risk of development of colorectal cancer after a colonoscopy with removal of 1 or 2 small adenomas is similar to persons who had a colonoscopy without finding or removal of any polyps. Persons without polyps are recommended to return in 10 years. The recommended follow up for persons with 1 or 2 small adenomas is 5 to 10 years. Do persons with 1 or 2 small adenomas need a colonoscopy exam before 10 years?

If Observational Data Are Convincing, Why the Need for a Large, Randomized Clinical Trial?

Observational studies did not account for the amount of surveillance colonoscopy that occurred in the patients with 1 or 2 small adenomas. That additional surveillance may have reduced the colorectal cancer risk. A prospective trial will clarify whether surveillance colonoscopy is needed before 10 years.

Will I Be Able to Find Patients Eligible For This Trial?

Yes! Patients undergoing first time screening colonoscopy have 1 or 2 small adenomas approximately 30% of the time. The study design also allows for the qualifying colonoscopy to have occurred up to four years prior.

What Are the Potential Impacts of the Results of FORTE?

If participants in the 10 year surveillance colonoscopy group have a colorectal cancer rate that is not inferior to the group with surveillance colonoscopy at 5 and 10 year surveillance, then in the future, a 5-year follow-up surveillance colonoscopy exam may not be needed. This would eliminate the need for an additional colonoscopy, which is costly, a time burden, and has medical risk.

Eligibility Criteria

- Participants ≥ 50 and < 70 years of age at the time of randomization.
- Participants with a first-time diagnosis of 1-2 non-advanced tubular adenomas (< 10 mm without tubulovillous or villous changes or high grade or severe dysplasia) **at a colonoscopy within 4 years prior to randomization.**
- Sessile serrated polyps/adenomas, as long as they do not meet the criteria for advanced adenomas, are considered non-advanced adenomas.
- Qualifying colonoscopy must be a complete colonoscopy with visualization of the cecum, with adequate cleansing, and with complete excision of polyps.

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