

CLINICAL STUDY PROTOCOL

Screening for Colorectal Neoplasms with the Fecal Testing: a Population-based Randomized Study

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ABSTRACT

Screening for stomach diseases and colorectal neoplasms with the fecal testing: a population-based randomized study

Growing body of evidences have shown that fecal immune test (FIT) outperform guaiac fecal occult blood test (gFOBT) in terms of sensitivity, neoplasm detection rate and public participation. Though direct outcome evidence is still lacking for FIT, it is anticipated to have higher colorectal cancer (CRC) mortality and incidence reduction compared with gFOBT. In Taiwan, nation-wide CRC screening program has been launched since the year of 2004 ,which provides biennial FIT screening for adults aged 50 to 75 years. Currently available data from the Bureau of Health Promotion has shown a significant stage-shift effect, an early indicator of screening effectiveness, by this screening program.

Nevertheless the aforementioned advantages of FIT, missed neoplasms and interval cancer still exists under the current one-day stool sampling method with biennial screening interval, which might affect the effectiveness of overall screening program. Increase the number of stool samples or shortening of screening interval may be helpful for early detection of clinically significant neoplasms but it remains unclear whether such an approach may lower the screenee compliance or public participation. Moreover, its impact on the demand of confirmatory colonoscopy and cost-effectiveness of the whole screening program is still largely unknown and need to be further investigated.

In this study, we aim to randomly allocate screening attendee to one of the

following four arms: one-day sampling with annual screening, one-day sampling with biennial screening, two-day sampling with annual screening, and two-day sampling with biennial screening. Participation rate, positive rates of FIT, detection rate for neoplasms, positive predictive value, and long-term outcome including cancer incidence and mortality will be calculated and compared among four groups. In addition, cost-effectiveness analysis will be also conducted using previously established Markov model of CRC natural history using the results ascertained from this trial.

The abundant results from this trial will be helpful for assessing the feasibility of increasing stool sampling and shortening screening interval in population setting, their long-term effects, and cost-effectiveness.

However, in Taiwan, although the incidence of colorectal cancer is rapidly increasing, *Helicobacter pylori*-related upper GI pathologies remain highly prevalent, which may imply that mass screening solely based on FIT could be insufficient as significant upper GI pathologies can be missed. Since FIT does not predict upper GI pathologies, the adjuncts of *H. pylori* stool-antigen test (HpSA) may be a potential candidate to realize a pan-detecting assay based on stool samples in a population in which both lower and upper GI lesions are equally prevalent.