Sir,

It is well known that gastric cancer (GC) is the second leading cause of cancer deaths in the world. In China, there is considerably geographic variation with very high rates in northern and the central parts of the country. In Linqu County/Shandong province, one of the highest rates not only in China but in the world is found, in 1980–1982 the age adjusted (world standard) death rate of GC was 70/100,000 in males and 25/100,000 in females. A recent study indicated that the crude mortality rates remained at this level since then. GC accounts for 40% of cancer deaths in Linqu County.

We describe shortly a randomized, controlled trial among 200,000 adult participants to prevent GC in Linqu County. The main target of this large population based intervention trial is to assess whether GC can be prevented by eradication of Helicobacter pylori (Hp) in the high-risk population. Secondary aims include the identification of genetic and serologic risk factors for Hp associated GC and neoplastic lesions.

There is growing evidence that treating Hp infection may lead to a reduced risk of subsequent GC. Combined data from previous trials seems to indicate this assumption. However, the protective effect is suggestive but not statistically significant. Thus a large population-based randomized trial is needed to prove that eradication of Hp reduces GC incidence rate.

This new study was launched in March 2011 – is a collaborative study between the Peking University School of Oncology (PUSO), the International Digestive Cancer Alliance (IDCA), Technische Universitaet Muenchen and Charles University (Prague).

We will screen approximately 200,000 residents aged 25 – 54 from 900 villages in Linqu County fulfilling the inclusive and exclusion criteria. The Hp status will be determined by 13 C-urea breath test (13C-UBT). We estimate the 140,000 participants will be positive. These subjects will be enrolled in the intervention study and randomized for two different antimicrobial treatment regimens with high or low dosage of omeprazole, tetracycline, metronidazole and bismuth by villages with 70,000 in each arm. All participants in both antimicrobial treatment groups will be followed for at least 10 years to assess the incidence and mortality rates of GC. This study has a power of 90% to determine whether eradication of Hp can effectively reduce the incidence by at least 21% at the 0.05 significance level.

The results of this study will have worldwide public health implications for all countries having a high incidence of GC. The study has been approved by the Institutional Review Board of PUSO and collaborating institutions.

References

