GISTAR study design

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MULTICENTRIC RANDOMIZED STUDY OF *H. PYLORI* ERADICATION AND PEPSINOGEN TESTING FOR PREVENTION OF GASTRIC CANCER MORTALITY

INTRODUCTION

Gastric cancer is an important global public health issue globally and in Eastern Europe. We propose to conduct a multi-center randomized trial in Latvia, Belarus, Russia and potentially other areas with high burden of the disease.

AIM

The aim of this study is to search for new intervention strategies to decrease mortality from gastric cancer in study area.

OBJECTIVES

The primary objective:

to determine if *H. pylori* screening followed by eradication of positive subjects and endoscopic follow-up of those with serological evidence of atrophic gastritis reduces mortality from gastric cancer in a high risk population among 40-64 years old subjects.

Secondary objectives are:

1. To determine retrospectively if biomarkers of chronic atrophic gastritis or others can select the group of subjects who require treatment to achieve gastric cancer reduction comparable to the primary objective.
2. To evaluate the rationale for volatile marker testing in exhaled breath for early identification of lesions in the stomach as well as other conditions related to increased risk.
3. To evaluate the role of diet, lifestyle factors and environmental factors in the development of gastric lesions.
4. To evaluate the impact of H. pylori eradication on selected medical conditions potentially associated with the infection (e.g. obesity, inflammatory bowel disease, dementia, circulatory diseases and esophageal diseases)

METHODS

30,000 men and women will be recruited into a randomized study

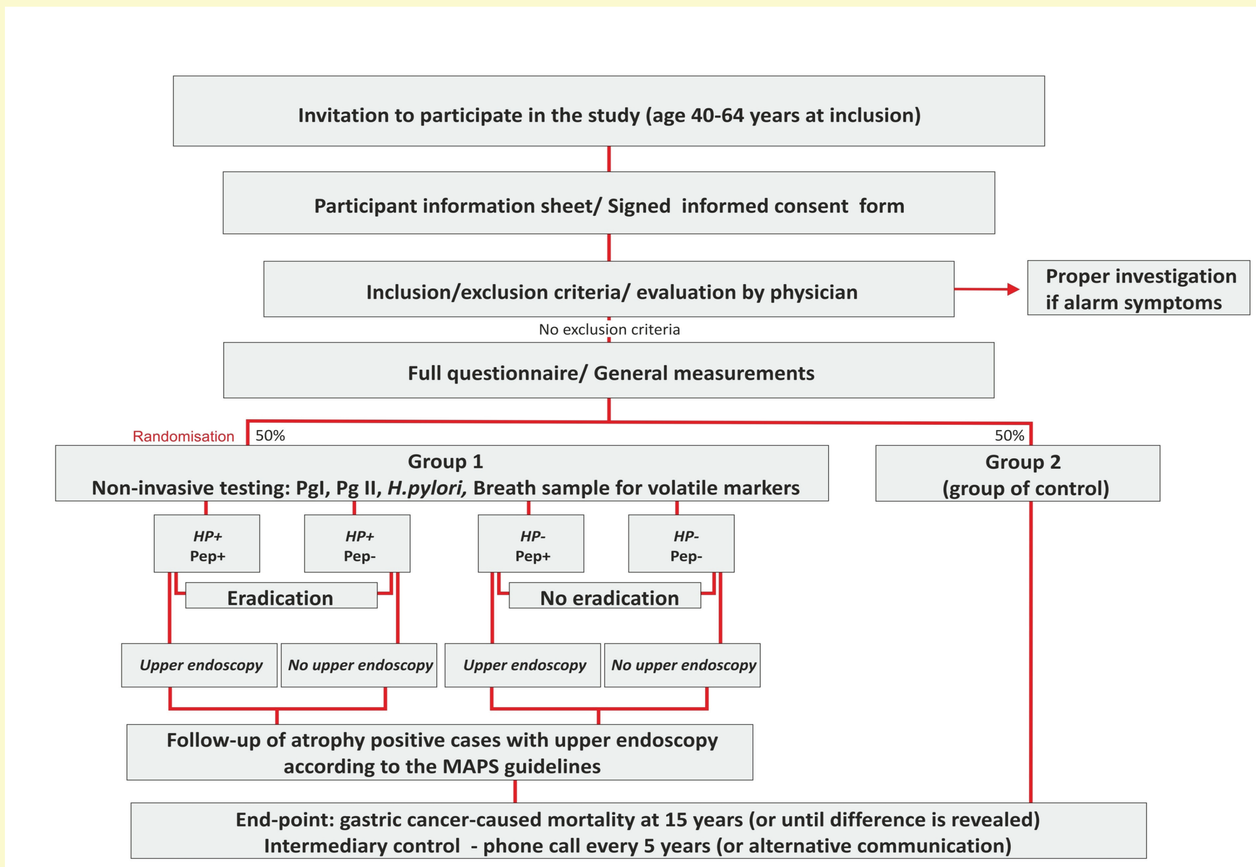
Initially a pilot study by enrolment approx. 2000 individuals in Latvia

Eligible subjects between 40-64 years of age at entry

For eligible participants who agree to participate and sign informed consent, a risk factor questionnaire will be administered and a complete medical evaluation will be performed at baseline.

Participants will be randomly assigned to either Group 1 (50%) or Group 2 (50%). (See Table 1)

Table 1. GISTAR study design



RESULTS

Altogether 30.000 individuals aged 40-64 years will be enrolled, providing 90% study power to detect at least 35% reduction in gastric cancer mortality at 15 years of follow-up;

Participants will be randomly allocated to one of two groups.

In the active investigation/management group those positive for *H. pylori* will be offered eradication therapy, individuals with decreased pepsinogen will be invited for endoscopy.

The control group will receive standard health care.

The primary endpoint for our trial will be the mortality difference from gastric cancer between the groups at 15 years or when enough cases accumulate to demonstrate a statistical difference.

CONCLUSIONS

The study is expected to provide valuable information on the utility for reduction in gastric cancer mortality of:

1) *H. pylori* eradication in adults on a population-basis, including among subjects who may already have pre-malignant lesions;

2) pepsinogen testing in screening settings.

Study has been approved by IARC Ethics Committee on March 26 th, 2013

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