Early Non-invasive Detection of Gastric Cancer with Plasma Pepsinogens in Croatian Patients

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ABSTRACT

Background:
Gastric cancer (GC) is the eight most common cancer and fifth leading cause of cancer deaths in Croatia. GC of the intestinal type is usually preceded by a chronic atrophic gastritis (CAG) which is a precancerous change in the stomach. Loss of chief cells leads to lower pepsinogens I (PGI) levels and PGI/PGII ratio in the peripheral blood. The potential usefulness of serum PG tests has been evaluated in many countries but this evidence has not resulted in generalized use in GC screening and prevention. Infection with Helicobacter pylori and its associated (CAG) is a strong risk factor for the development of both atrophic gastritis and gastric cancer. Screening programs have led to an improvement of overall 5-year survival rate for gastric cancer in Japan and PG method was suggested to reduce mortality from gastric cancer. The primary objective of the study is to assess if the addition of serum reagents for GC detection will improve detection of suspicious GC. The secondary objectives of the study are to evaluate serum GC reagents in Croatian population, evaluate sensitivity and specificity of reagents, and to determine if these reagents can be part of routine diagnostic procedures for gastric cancer diagnosis.
Trial design:
This single-center trial, will randomize 120 patients suspected to have GC. Inclusion criteria for the study are: signed informed consent, life expectancy > 12 weeks, and exclusion criteria will be: previous oncological treatments for any malignancy, current us age of IPP or NSAIDs medication, poor ECOG performance status ≥3, known history of H. pylori eradication treatment or gastric surgery. Patients will be divided in 1:1:1 ratio between groups. Experimental group of patients will be patients already in diagnostic procedure for possible GC, Confirmative group will be patients who already have patohistologicaly confirmed gastric adenocarcinoma and Control group will be patients with endoscopically and clinically excluded GC disease. We will use cut off points to evaluate gastric cancer risk: PGI ≤ 70 and PGI/II ratio ≤ 3.0. Associations will be analyzed using conditional logistic regression models to estimate adjusted OR and 95% CI for the association between GC and plasma concentrations of PG, or th PG1:2 ratio.
Clinical trial identification
EudraCT number 2016-000519-34 has been issued for your Sponsor's Protocol Code Number 1068.

BACKGROUND

Gastric cancer (GC) is the eight most common cancer and fifth leading cause of cancer deaths in Croatia. Despite improvements in cancer diagnosis and therapy, about two-thirds of patients with GC are still diagnosed with advanced cancer. GC of the intestinal type is usually preceded by a chronic atrophic gastritis (CAG) which is a precancerous change in the stomach. Loss of chief cells leads to lower pepsinogens I (PGI) levels and PGI/PGII ratio in the peripheral blood. The potential usefulness of serum PG tests has been evaluated in many countries but this evidence has not resulted in generalized use in GC screening and prevention. Infection with Helicobacter pylori and its associated (CAG) is a strong risk factor for the development of both atrophic gastritis and gastric cancer. Screening programs have led to an improvement of overall 5-year survival rate for gastric cancer in Japan and PG method was suggested to reduce mortality from gastric cancer. The primary objective of the study is to assess if the addition of serum reagents for GC detection will improve detection of suspicious GC. The secondary objectives of the study are to evaluate serum GC reagents in Croatian population, evaluate sensitivity and specificity of reagents, and to determine if these reagents can be part of routine diagnostic procedures for gastric cancer diagnosis

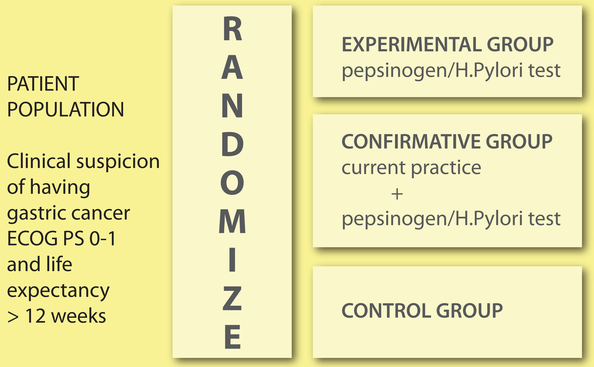
METHODS

This single-center trial, will randomize 120 patients suspected to have GC. Inclusion criteria for the study are: signed informed consent, life expectancy > 12 weeks, and exclusion criteria will be: previous oncological treatments for any malignancy, current usage of IPP or NSAIDs medication, poor ECOG performance status ≥3, known history of H. pylori eradication treatment or gastric surgery. Patients will be divided in 1:1:1 ratio between groups. Experimental group of patients will be patients already in diagnostic procedure for possible GC, Confirmative group will be patients who already have patohistologicaly confirmed gastric adenocarcinoma and Control group will be patients with endoscopically and clinically excluded GC disease. We will use cut off points to evaluate gastric cancer risk: PGI ≤ 70 and PGI/II ratio ≤ 3.0. Associations will be analyzed using conditional logistic regression models to estimate adjusted OR and 95% CI for the association between GC and plasma concentrations of PG, or th PG1:2 ratio.

KEY ELIGIBILITY CRITERIA

Inclusion criteria:
ability to understand, and willingness to sign, a written informed consent form and to comply with scheduled visits, diagnostic plans, laboratory tests (blood testing), and other study procedures
life expectancy > 12 weeks,
age 18 years or older
and exclusion criteria:
previous oncological treatments for any malignancy unless cervix itd ,
current usage of IPP or NSAIDs medication,
poor ECOG performance status ≥3,
known history of H. pylori eradication treatment or gastric surgery.

STUDY DESIGN



OUTCOME MEASURES

The primary objective of the study is to assess if the addition of serum reagents for GC detection will improve detection of suspicious GC.
The secondary objectives of the study are to evaluate serum GC reagents in Croatian population, evaluate sensitivity and specificity of reagents, and to determine if these reagents can be part of routine diagnostic procedures for gastric cancer diagnosis.

STATUS

Activated in November 2015
51 patients screened

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ACKNOWLEDGEMENTS

The study is supported by Eiken Chemical Co.Ltd, Tokyo, Japan

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