

The proportion of patients with improvement for each symptom will be compared between the treatment and placebo groups using the Fisher's exact probability test.

### 3.2.2 The change of GSRS scores before and after drug administration

The changes of the overall GSRS scores and subscale scores will be calculated from the pre-administration values and 8 weeks post-administration. The mean changes of the scores before and after drug administration between the treatment and placebo group will be evaluated by using the student's t-test.

### 3.2.3 Subgroup analysis of gender and *H. pylori* infection

We will analyze the GPA, Likert scale-based dyspepsia symptoms, and GSRS based on gender and *H. pylori* infection stratifications.

### 3.2.4 Analysis of blood plasma ghrelin

- Analyses will be conducted for each gender separately.
- Comparison whether there are differences in the mean values between the treatment and placebo groups (verification of randomization) before administration
- Evaluation of relationships between ghrelin values before administration and dyspepsia symptoms (using the Likert scale) using Spearman's correlation analysis
- Evaluation of mean values between treatment and placebo groups 8 weeks post-administration by using the Student's *t* test

## 4. Safety endpoints

Safety will be evaluated with summary of adverse events.

## II. 研究成果の刊行に関する一覧表

● 論文発表

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<u>春日井邦夫</u> 、舟木康、飯田章人、小長谷敏浩、松永昌宏、小笠原尚高、佐々木誠人	上部消化管症状を捉える	Frontiers in Gastroenterology	16(3)	188-98	2011
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