AstraZeneca

Clinical Study Report Synopsis

Drug Substance	Not applicable
Study Code	NIS-GSE-DUM-2009/1
Edition Number	Version 1.0
Date	2010-05-03

A prospective, non interventional study to evaluate the effects on quality of life, symptoms, and productivity in patients with gastroesophageal reflux disease (GERD) after 6 weeks structured treatment in an occupational health care setting

Study dates: First subject enrolled: 2009-04-16
Last subject last visit: 2009-06-29

Phase of development: NA

International Co-ordinating Investigator:

Sponsor's Responsible Medical Officer:

This study was performed in compliance with Good Clinical Practice, including the archiving of essential documents.

Study centre(s)

This study was performed at Hälsocenter, AstraZeneca Södertälje, Sweden.

Publications

None at the time of writing this report.

Objectives and criteria for evaluation

The study aimed to evaluate if a GERD management program, in accordance with current regional recommendations, in an occupational health care setting, has an impact on health related quality of life (HRQoL), symptoms, and productivity in GERD patients.

Primary objectives

• To describe the change in HRQoL in GERD patients after a 6-week period (EQ-5D)

Secondary objectives

• To describe the change in symptoms in GERD patients after a 6-week period (GerdQ)
• To describe the change in productivity in GERD patients after a 6-week period (WPAI-GERD)
• To describe the change of current GERD treatment after a 6-week period

Study design

Employees diagnosed with GERD at Hälsocenter and taken care of according to the regional GERD program were asked to participate in the study. At Visit Day 0 the patients were asked to answer the EuroQoL-5D (EQ-5D), GerdQ, and Work Productivity and Activity Impairment in GERD patients (WPAI-GERD) questionnaires, and additional questions about demography, relevant medical history, current relevant medication, tobacco and alcohol consumptions, and estimated cost for over-the-counter (OTC) medication. After 6 weeks the patients were to complete the EQ-5D, GerdQ, and WPAI-GERD questionnaires, and also fill in the current relevant medication.

Target subject population and sample size

The target population was employees at AstraZeneca, R&D, Södertälje, with symptoms of GERD.
Each patient was to meet all of the inclusion criteria and none of the exclusion criteria for this study. Under no circumstances could there be exceptions to this rule.

Inclusion criteria

For inclusion in the study, subjects had to fulfil all of the following criteria;

1. Provision of informed consent prior to any study specific procedures
2. Female and/or male aged $\geq$ 18 years
3. Diagnosis of GERD confirmed
4. Prescription of GERD treatment or already receiving GERD treatment

Exclusion criteria

Any of the following was regarded as a criterion for exclusion from the study:

1. Current participation in a clinical study or participation in a clinical study during the last 30 days
2. Any symptom suggesting a need for further investigation

This was a descriptive study and no formal sample size calculation has been made.

Investigational product and comparator(s): dosage, mode of administration and batch numbers

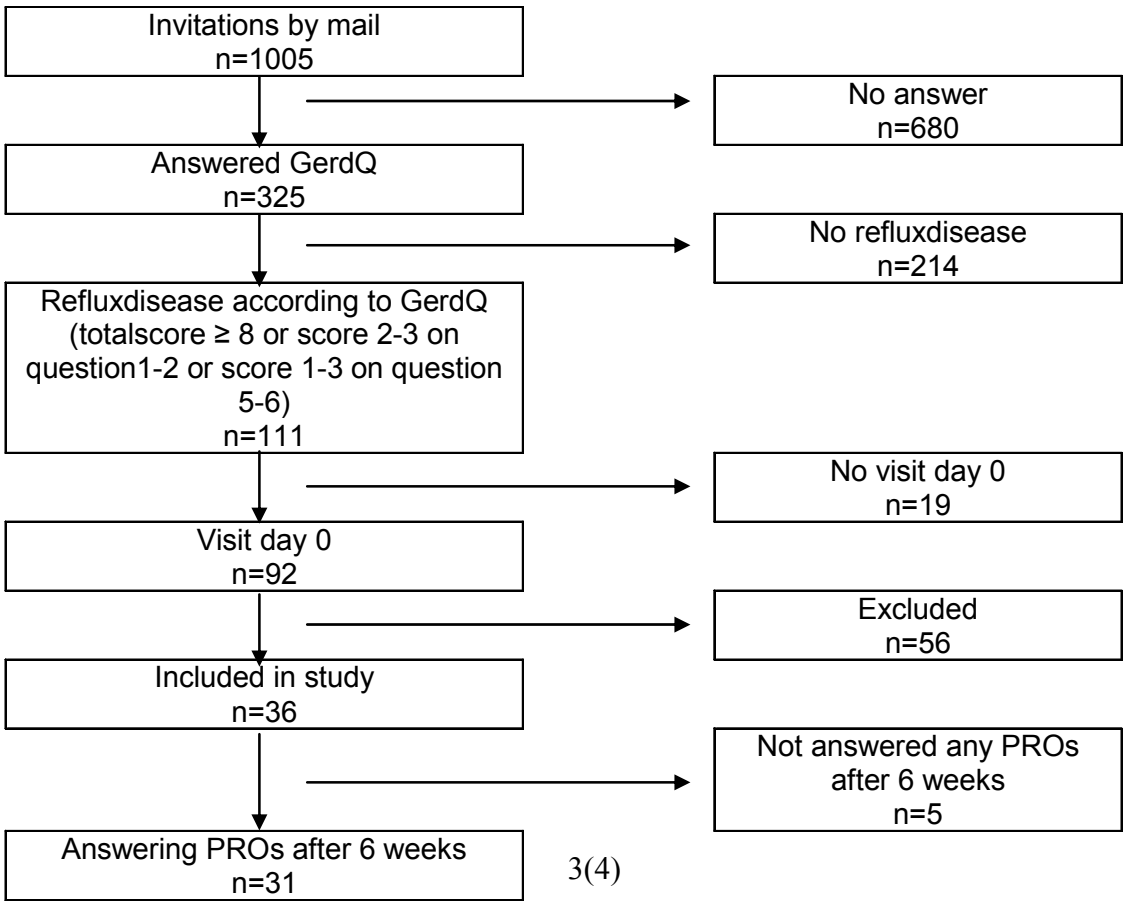
Not applicable

Statistical methods

The baseline population was analyzed by descriptive statistics.
Change in EQ-5D, GerdQ, and WPAI-GERD between end-of-study and baseline was analyzed using an analysis of variance (ANOVA) model with baseline values as a covariate.

Subject population

Figure 1. *Disposition*



Summary of efficacy results

The GerdQ questionnaire was sent to 1005 employees, 325 responded and 111 (11%) fulfilled the criteria for un-treated or under-treated GERD. Visit 1 was conducted by 92 patients, out of which 36 were enrolled into the study (24 women (67%), mean age 48.4 years; normal BMI 67%, 33% overweight or obese, 12% smokers). Visit 2 was conducted by 31 patients.

At visit 1 32% of all patients scored ≥ 8 points on GerdQ, and they were all under-treated (symptoms > 2 days / week and/or sleep disorder) according to GerdQ criteria for under-treatment. At visit 2 after 6 weeks the corresponding values were 6.5%, respectively 35.5%.

The patients' health related quality of life measured as utility weights (0 = death and 1 = perfect health) improved from 0.801 to 0.852 between visits 1 and 2. The proportion of patients who rated themselves as in perfect health more than doubled, from 17 to 41%.

At baseline patients had the following treatment: 29 patients (80%) omeprazole 20 mg, 1x1, 5 patients (12%) esomeprazole 40 mg 1x1, and one patient (3%) received esomeprazole 20 mg 1x1. The patients who had persistent symptoms after 2 weeks (11 patients, 35%) received a more effective acid inhibition by, switching to esomeprazole 40 mg daily for 10 patients and for omeprazole 40 mg daily for a patient.

The monetary value of the total GERD related work productivity loss (absence from work + reduced productivity while at work) was reduced by SEK 343 per week per patient – from SEK 971 to SEK 628 - during the study period.

Summary of pharmacokinetic results

Not applicable.

Summary of pharmacodynamic results

Not applicable.

Summary of pharmacogenetic results

Not applicable.

Summary of safety results

Not applicable.