
Clinical Study Report Synopsis

Drug Substance	None
Study Code	NIS-RMY-SYM-2009/1
Edition Number	1
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**SATISFACTION LEVEL AND ASTHMA CONTROL AMONG
MALAYSIAN ASTHMA PATIENTS ON SYMBICORT MAINTENANCE
AND RELIEVER THERAPY (SMART) IN THE PRIMARY CARE
SETTING (SMARTEST STUDY)**

Study dates:	First subject enrolled: 1 Aug 2009 Last subject last visit: 31 Jan 2010
Phase of development:	NIS

Objectives and criteria for evaluation**Table S1 Primary and secondary objectives and outcome variables**

Objectives	Outcome variables	Type
Primary To characterize the level of asthma control and patient satisfaction amongst diagnosed asthma sufferers who are currently receiving Symbicort Maintenance and Reliever Therapy (SMART) in Malaysia	Primary Current Asthma Control Test (ACT) Score & Satisfaction of Asthma Treatment Questionnaire score (SATQ)	Patient Reported Outcome

Study design

Participants will be recruited via their physician and given an interviewing pack, including a self-completion questionnaire. Participants will then complete and return the questionnaire to their physician's office

Target subject population and sample size

The patient population that was observed in the NIS, fulfilled all of the following criteria:

1. Provision of informed consent
2. Female or male patients aged 18-59 years
3. Diagnosed asthma patients who have been prescribed Symbicort SMART (1 or 2 inhalation twice daily & when required) for at least three months prior to recruitment and still taking the medication as indicated by their physician
4. Patients requiring short courses (3-5 days) of oral corticosteroid/methylxanthines less than twice a month can be included
5. Able to participate in interview independently.

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

None

Duration of treatment

None

Statistical methods

Epidemiological methods was used for the analysis of collected data and completed by a nominated CRO. Data was summarised descriptively.

Subject population

228 patients enrolled from 44 clinic centres from Kuala Lumpur, Penang, Johor and other areas around Malaysia.

- Gender
 - 59% female
 - 41% Male
- Age
 - 12% under 30 years old
 - 28% aged between 30 – 39 years
 - 34% aged between 40 – 49 years
 - 26% aged between 50 – 59 years

- Ethnic Group
 - 45% Chinese
 - 38% Malay
 - 13% Indian
 - 4% others
- Working Status
 - 63% working full time
 - 37% Not working full time
- Education Level
 - 22% tertiary/degree
 - 12% post secondary
 - 59% secondary
 - 4% primary or below
 - 3% still in education

Summary of results

228 patients recruited, 189 patients (83%) were well-controlled as assessed by the Asthma Control Test questionnaire. Seventy percent of the well-controlled patients did not need to use their reliever on most occasions. The overall SATQ score that was obtained in this study for well-controlled patients was 5.8 indicating a high satisfaction level. For all domains in SATQ, both patient groups indicated high satisfaction level (effectiveness, ease of use, burden of medication, side effects and worries). Between well controlled and not well controlled group, there was a significant difference in the effectiveness and burden of medication domain as well as the overall score.

Asthma was controlled in 189 (83%) patients (total control in 69 and well control in 120 patients). The overall SATQ score for patients with controlled asthma was 5.8. Controlled patients had overall SATQ score of 5.8 and uncontrolled had satisfaction of 5.2 with a p-value 0.0087

Summary of safety results

No patient safety issue reported in patients recruited in the study