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Appendix 1

PATIENT' S RECORD
(FOR PHYSICIAN)

Code No.....

Name:.....

Age

Sex: 1.() male 2.() female

Occupation : 1.() government officer 2.() housewife 3.() Merchant
 4.() student 5.() constuction workers
 6.() factory workers 7.() white collars
 8.() farmers 9.() others

Duration of nasal symptom

History of allergy in the family 1.() presence 2.() absence

Weight of nasal spray at the first time gm.

Weight of nasal spray at the end of the trial gm.

NASAL SYMPTOMS SCORES DIARY CARD
(RUN-IN PERIOD : FOR PATIENTS)

Code No.

Name

First week run-in period

1. Individual nasal symptom score (sneezing, nasal stuffiness, nasal discharge):
Please score your individual nasal symptom using scale and record before bedtime(about 9.00 p.m.) and after wake up in the morning (about 6.00 am.) as
- 0 = no symptom
- 1 = mild symptom (not troublesome)
- 2 = moderate symptoms (frequently troublesome but not sufficient to interfere with normal daily activity or night time sleep)
- 3 = severe symptoms (sufficiently troublesome to interfere with normal daily activity or night time sleep)

Day (date)	1()		2()		3()		4()		5()		6()		7()	
	N	M	N	M	N	M	N	M	N	M	N	M	N	M
Congestion														
Rhinorrhea														
Sneezing														

N = at night before bedtime, M = early in the morning after wake up

3. Individual nasal symptom score (sneezing, nasal stuffiness, nasal discharge):

Please score your individual nasal symptom using scale and record before bedtime(about 9.00 p.m.) and after wake up in the morning (about 6.00 am.)

0 = no symptom

1 = mild symptom (not troublesome)

2 = moderate symptoms (frequently troublesome but not sufficient to interfere with normal daily activity or night time sleep)

3 = severe symptoms (sufficiently troublesome to interfere with normal daily activity or night time sleep)

Day(date)	8()		9()		10()		11()		12()		13()		14()	
	M	N	M	N	M	N	M	N	M	N	M	N	M	N
Congestion														
Rhinorrhea														
Sneezing														

N = at night before bedtime, M = early in the morning after wake up

4. Overall total nasal symptoms assessment after completion one week of using nasal spray. Please mark (/) in the suitable bracket (criteria as 2)

() score 0 () score 1 () score 2 () score 3 () score 4

5. Mark (/) if there is any nasal symptoms as noted and any adverse reaction. Write any other adverse reactions.

Day (date)	8 ()	9 ()	10()	11()	12 ()	13()	14()
Purulent rhinorrhea or watery rhinorrhea +/- fever ,+ myalgia							
Adverse reaction							
1.epistaxis							
2.nasal irritation							
3.nasal itching							
4.sneezing							
5. dry nose							
6.dry throat							
7.Others(please specify)							

3rd week

1. Mark (/) for the actual action of using the nasal spray at night

Day(date)	15()	16()	17()	18()	19()	20()	21()
Use nasal spray							
Do not use n.s.							

2. Overall nasal symptoms assessment by the patient.at the time before using the next nasal spray. Mark (/) in the suitable space by using overall nasal symptom rating scale as follows

0 = symptoms are worse comparing with the baseline(run-in period)

1 = same symptoms comparing with the baseline

2 = symptoms can be minor controlled comparing with the baseline

3 = symptoms can be substantially controlled comparing with the baseline

4 = symptoms can be totally controlled

Day(date)	15()	16()	17()	18()	19()	20()	21()
Score 0							
Score 1							
Score 2							
Score 3							
Score 4							

3. Individual nasal symptom score (sneezing, nasal stuffiness, nasal discharge):

Please score your individual nasal symptom using scale and record before bedtime(about 9.00 p.m.) and after wake up in the morning (about 6.00 am.)

0 = no symptom

1 = mild symptom (not troublesome)

2 = moderate symptoms (frequently troublesome but not sufficient to interfere with normal daily activity or night time sleep)

3 = severe symptoms (sufficiently troublesome to interfere with normal daily activity or night time sleep)

Day(date)	15()		16()		17()		18()		19()		20()		21()	
	M	N	M	N	M	N	M	N	M	N	M	N	M	N
Congestion														
Rhinorrhea														
Sneezing														

4. Overall total nasal symptoms assessment after completion two week of using nasal spray. Please mark (/) in the suitable bracket (criteria as 2)

() score 0 () score 1 () score 2 () score 3 () score 4

4th week

1. Mark (/) for the actual action of using the nasal spray at night

Day(date)	22()	23()	24()	25()	26()	27()	28()
Use nasal spray							
Do not use n.s.							

2. Overall nasal symptoms assessment by the patient.at the time before using the next nasal spray. Mark (/) in the suitable space by using overall nasal symptom rating scale as follows

0 = symptoms are worse comparing with the baseline(run-in period)

1 = same symptoms comparing with the baseline

2 = symptoms can be minor controlled comparing with the baseline

3 = symptoms can be substantially controlled comparing with the baseline

4 = symptoms can be totally controlled

Day(date)	22()	23()	24()	25()	26()	27()	28()
Score 0							
Score 1							
Score 2							
Score 3							
Score 4							

3. Individual nasal symptom score (sneezing, nasal stuffiness, nasal discharge):

Please score your individual nasal symptom using scale and record before bedtime(about 9.00 p.m.) and after wake up in the morning (about 6.00 am.)

0 = no symptom

1 = mild symptom (not troublesome)

2 = moderate symptoms (frequently troublesome but not sufficient to interfere with normal daily activity or night time sleep)

3 = severe symptoms (sufficiently troublesome to interfere with normal daily activity or night time sleep)

Day(date)	22()		23()		24()		25()		26()		27()		28()	
	M	N	M	N	M	N	M	N	M	N	M	N	M	N
Congestion														
Rhinorrhea														
Sneezing														

N = at night before bedtime, M = early in the morning after wake up

4. Overall total nasal symptoms assessment after completion third week of using nasal spray. Please mark (/) in the suitable bracket (criteria as 2)

() score 0 () score 1 () score 2 () score 3 () score 4

5. Mark (/) if there is any nasal symptoms as noted and any adverse reaction. Write any other adverse reactions.

Day (date)	22 ()	23 ()	24()	25()	26 ()	27()	28()
Purulent rhinorrhea or watery rhinorrhea +/- fever ,+ myalgia							
Adverse reaction							
1.epistaxis							
2.nasal irritation							
3.nasal itching							
4.sneezing							
5. dry nose							
6.dry throat							
7.Others (please specify)							

Appendix 2

CONSENT FORM

I have been informed that Dr. Sanguansak Thanaviratananich is conducting a study of budesonide trial for Thai adults with perennial rhinitis. The purpose of this study is to evaluate the therapeutic effect of budesonide for controlling nasal symptoms.

I have been informed of the efficacy of budesonide and the adverse reactions that may occur . After reading the written information of the trial, I understand the purpose and details of the study.

I, being (the patient myself),(the guardian of)(the patient's name), agree (this patient) to participate in this study.

I understand that the agreement of participation in this study is entirely voluntary and that I may withdraw my consent to participate at any time without penalty and without in any way affecting the health services.

I have an opportunity to ask questions about this study and if I have further question about this study, I may contact the researchers in Srinagarind Hospital on Tel. 242343-6 ext. 3730, 3542.

Subject's (Patient's) signature.....

Subject's guardians signature..... (relation:.....)

Physician's name

The witness' signature.....

The witness' name.....

CURRICULUM VITAE

Mr Sanguansak Thanaviratananich was born on January 17, 1957 in Khon Kaen, Thailand. He graduated for his doctor of medicine degree from Siriraj Hospital, Mahidol University, Thailand. He further studied in Otolaryngology and got the proficiency diploma in Otolaryngology in 1987.

He has been enrolled in the Master's degree in Health Development Program at Faculty of Medicine, Chulalongkorn University, Bangkok under the Thai Certc Consortium since June 1997. He is now a lecturer of the department of Otolaryngology, Faculty of Medicine, Khon Kaen University, Thailand.

