
Clinical Study Report Synopsis

Drug Substance	None
Study Code	NIS-RTR-DUM-2011/1
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Cross-sectional observational study to investigate the effects of chronic obstructive pulmonary disease on daily life activities

COPD LIFE Study

Study dates: First subject enrolled: 29.03.2011
Last subject last visit: 30.06.2011

Phase of development: This is not a drug trial

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

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Study centre(s)

A total of 41 centers in Turkey participated in this study.

Publications

None at the time of writing this report

Objectives and criteria for evaluation

Table S1 presents study objectives and corresponding variables.

Table S1 Primary and secondary objectives and outcome variables

Objectives	Outcome variables	Type
Primary	Primary	
To evaluate the effect of COPD on daily life activities in COPD patients	Daily life activities: The distribution of patients according to their answers (yes / no / no idea) to the patient questionnaire about limiting effects of COPD on their daily life activities.	NA
Secondary	Secondary	
To determine socio-demographic profile of the COPD patients	Socio-demographic profile: The distribution of patients according to several basic characteristics such as age, gender, living place and conditions, marital status, etc.	NA
To determine daily life activity profiles and needs of COPD patients	Daily life activities and needs: The distribution of patients according to their answers to the questions about how they spend their day.	NA
To determine patients' expectations from COPD treatment	Treatment expectations: The distribution of patients according to their expectations from their COPD treatment.	NA

Study design

This study is a local, multicenter cross-sectional observational study conducted at 41 centers in Turkey. No diagnostic or follow-up procedures were done other than those of routine daily practice. Data for this study collected from the patient, her/his medical records and the physician only if available.

Target subject population and sample size

Patients over 45 years of age with COPD and FEV1/FVC <70% who applied to a participant physician of this study for outpatient treatment for any reason, either a smoker or used to be a smoker once (≥ 10 package years) and gave consent for the use of their medical data were included in the study. The exclusion criteria were: An exacerbation of COPD that still lasts or that was experienced within last 3 months, History of asthma and/or allergic rhinitis, The presence of another important respiratory disease.

It was aimed to include all patients fulfilling patient selection criteria admitting to the study centers. Therefore, it was estimated that during the patient selection period, 10-20 such patients might be included at each center; and a total of 497 patients were included.

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

Not applicable.

Duration of treatment

Not applicable.

Statistical methods

Data regarding socio-demographic characteristics and daily activities of the patients, the effect of COPD on daily activities and therapeutic expectations by the patients were summarized by descriptive statistics. Categorical data were summarized as n and %; and numeric data were expressed as mean, median, standard deviation, etc. Comparisons were done by Chi-square test. The level of statistical significance was considered 0.05.

Subject population

A total of 497 patients from 41 centers were included in the study. There was only single study visit and all patients could have been reached for the telephone visit.

Summary of primary endpoint results

Approximately half of the patients (45.3%) declared that COPD limits their working and almost 90% of the patients declared that the disease interferes their daily life to some extent (20.9% slightly, 42.3% moderately, 29.6% very much); despite this, 55.7% of the patients should go out every day, 16.5% every other day and the remaining sometimes (Table S2).

Table S2. The effect of COPD on daily life activities in COPD patients

	n (%)			
	Yes	Partially	No idea	No
Is your lung disease a limitation for your work?	225 (45.3)	55 (11.1)	24 (4.8)	193 (38.8)
Can you go out despite your lung disease?	453 (91.1)	--	2 (0.4)	42 (8.5)
How frequent would you like to / should go out of your house?	Everyday	Every other day	Sometimes	
	277 (55.7)	82 (16.5)	138 (27.8)	--
How much your lung disease influences your daily life?	Very much	Moderately	Slightly	Not at all
	147 (29.6)	210 (42.3)	104 (20.9)	36 (7.2)

A significant relationship between COPD grade and the influence of the disease on daily life activities (p=0.002).

Table S3. Effect of COPD on daily life activities of the patients according to their disease grade

COPD grade		How much your lung disease influences your daily life?				Total
		Very much	Moderately	Slightly	Not at all	
Mild	n	9	15	16	5	45
	%	20.0	33.3	35.6	11.1	100.0
Moderate	n	68	101	46	15	230
	%	29.6	43.9	20.0	6.5	100.0
Severe	n	46	79	32	11	168
	%	27.4	47.0	19.0	6.5	100.0
Very severe	n	24	15	10	5	54
	%	44.4	27.8	18.5	9.3	100.0
Total	n	147	210	104	36	497
	%	29.6	42.3	20.9	7.2	100.0

$P = 0.002$ (Mantel Haenzsel test)

The most affected activities were climbing the stairs (66.6%), walking (45.3%) and doing housework (43.1%) (Table S4).

Table S4. How easy the patients can perform essential daily life activities

	Can you perform the following daily life activities easily?			
		Yes	No	No idea
Climbing the stairs	n	166	331	0
	%	33.4	66.6	0
Walking	n	272	225	0
	%	54.7	45.3	0
Houseworks	n	148	214	135
	%	29.8	43.1	27.2
Baby sitting	n	140	193	164
	%	28.2	38.8	33
Sexual intercourse	n	143	177	177
	%	28.8	35.6	35.6
Going to for shopping	n	348	148	1
	%	70	29.8	0.2
Cooking / eating	n	382	91	24
	%	76.9	18.3	4.8
Sleeping	n	420	75	2
	%	84.5	15.1	0.4
Bathing	n	427	70	0
	%	85.9	14.1	0
Dressing	n	451	46	0
	%	90.7	9.3	0

	Can you perform the following daily life activities easily?			
		Yes	No	No idea
Shaving / combing / make-up	n	463	34	0
	%	93.2	6.8	0
Going to the toilette	n	473	24	0
	%	95.2	4.8	0
Face washing in the morning	n	486	11	0
	%	97.8	2.2	0

Summary of secondary endpoint results

Socio-demographic profile of the COPD patients

- The mean (SD) age of the 497 patients included in the study was 63.3 (9.3) years; 89.9% were males; and the majority was at least received primary school education.
- Most (64.2) patients were living at city centers, 23.5% in towns and 12.3% in villages.
- Almost all (93.2%) were married and living with their families (%98).
- The patients should take care of a mean (SD) of 2.2 (1.9) (median 2; min-max 0-15) and provide living expenses for 2.1 (1.9) (median 2; min-max 0-15) individuals.
- The majority of the patient were not actively working (13.7% no job; 60.8% retired and not doing any other job); while others were to work at various jobs; and only 56.3% declared that they had enough income for a living. Almost half (47.9%) of the patients were to earn the living expenses of the family that was significantly higher for those <65 years of age (p=0.002).

Daily life activity profiles and needs of COPD patients

- A quarter of the patients declared that they could not take care of themselves without help, while 75.9% could do so. The longest period of time was spend by laying down (mean (SD) 9.3 (2.7) hours), followed by watching TV / listening music (5.0 (3.1) hours), out of the house and work (3.4 (2.8) hours), at the office / working (2.2 (3.8) hours), newspaper / book reading (1.0 (1.3) hours) and doing housework (0.6 (1.5) hours).

Patients' expectations from COPD treatment

- The first most frequent answers to the question of “What would you like your medication provides you to do more easily” were:
 - breathing (%24.1),
 - walking (%17.1), and

- climbing the stairs (%11.7).
- In response to the question of “If you were a doctor, which problems of the patients with lung disease would you wish to preferably treat?”, 43.3% chose dispnea, 11.1% coughing.

Summary of safety results

Not applicable.