

**Effect of Vitamin D3 on Lung Function and Exercise
Tolerance in D3 Deficient COPD Patients**

ClinicalTrials.gov ID: NCT03781895

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INFORMED CONSENT STATEMENT

Title of the study: Effect of vitamin D₃ on lung function and exercise tolerance in D₃ deficient COPD patients.

You are being asked to take part in a research study. Your participation is voluntary. Before agreeing to participate in this study, it is important that you read the following explanation of the study, if you do not understand what you are reading, do not sign it. Please ask the researcher to explain anything, you do not understand. If you decide to participate, you will be asked to sign this form and a copy will be given to you.

Purpose of the study: The present study will be conducted to assess lung function status in male patients with stable COPD by spirometric lung function variables before and after supplementation therapy for a period of 3 months.

This study may find out the benefit of vitamin D₃ on lung function in COPD patients.

Explanation of procedures: The researcher will take an interview and will do general examination of the body. Then the spirometric variable will be measured and exercise tolerance, oxygen saturation, the level of dyspnea and fatigue (Borg scale) will be measured before and after six minute walk test . Then 5 ml venous blood will be collected under all aseptic precaution. The same procedure will be done on his follow up.

Risks and discomfort: This study involves almost no physical risk. The researcher will be cautious in using the measurement tools so that the procedure does not harm you physically. However, while drawing the blood sample, the subject may experience slight discomfort, but it will be negligible. Adequate precautions will be taken to avoid any error.

Withdrawal without prejudice: Each participant is free to withdraw the consent and discontinue participation in this study at any time.

Confidentiality: Your identity in this study will be treated as confidential. Your name or identity will not be linked in any way to the research study.

Costs and payments to subjects for participation in research: There is no financial support (compensation) for your participation in this research.

Available medical treatment for research related injuries: If you are injured as a direct result of taking part in this research study, emergency medical care will be provided by transporting to your personal doctor or medical centre.

Questions: Any question concerning the research, study participants can call Dr. Samia Hassan at 0191174400.

Authorization: I have read and understood this consent form and I volunteer to participate in this research study, but I understand that my consent does not take away any legal rights in the case of negligence or other legal fault of anyone who is involved in this study.

Participant's

Signature:.....

Date:.....

DATA SCHEDULE

Title: Effects of Vitamin D₃ on lung functions & exercise tolerance in male COPD patients

ID No: _____ SL No: _____ Date:.....

Subject information

Name: _____ Age (years): _____

Contact address: _____

Permanent Address: _____

E-mail ID : _____

Contact No: Tel: _____ Cell: _____

Occupation: Dependent-1; Student-2; Unemployed-3; Business-4; Service-5; Day labour-6;

Education: Illiterate-0; primary-1; High School-2; SSC-3; HSC-4; Graduate-5; Masters-6;

Marital status: Married-1; Unmarried-2; Widower-3; Separated-4; Divorced-5; Live together-6;

Socioeconomic status:

Monthly income (Taka):

Number of family members:

Residence: Urban/Rural

Personal History

1. Smoking habit: Current smoker/Past smoker

Packs- year:

Duration of smoking:

Stopped for (in years, in case of past smoker):

2. Marital status: Married/Unmarried.

3. Past medical history:

History of hypertension: Yes/No
History of Cardiac disease: Yes/No
History of Liver disease: Yes/No
History of Psychic and neurological disorder: Yes/No.
History of diabetes mellitus: Yes/No
Others: Yes/No
(If yes)
Duration of disease:

4. Drug History:

5. Anthropometrical data:

Height: cm. Weight: Kg.
BMI: kg/m²

6. General examination : (present = +, absent = -)

Anemia: - / + / ++ / +++
Jaundice: - / + / ++ / +++
Pulse rate:beat/min.
Cyanosis: - / + / ++ / +++
Clubbing: - / +
Edema : - / +

Ascites : -/+

BP: Systolic : mm of Hg.

Diastolic: mm of Hg

7. Systemic examination:

P/A examination:

Kidney- Palpable/Not

Spleen- Palpable/Not

Liver- Palpable/Not

Heart- Normal/Abnormal.

Respiratory System:

Shape of the chest - Normal/ Abnormal

Movement of chest- Abdominothoracic/
Thoracoabdominal

Tracheal position - Central/Shifted to right /Shifted
to left

Use of accessory respiratory muscles - Yes/No

Percussion note - Dull/Resonance

Auscultation -
Clear/Creaps/Ronchi

Breath sound - Vesicular/Bronchial

Added sound- Yes/No.

Study variables:

Lung Function variables	PV	MV	% of PV	MV	% of PV
		(day 0)	(day 0)	(day 90)	(day 90)
FVC:	(L)				
FEV ₁ :	(L)				
FEV ₁ /FVC	(%)				
PEFR:	(L/S)				
FEF ₂₅₋₇₅	(L/S)				
MEF ₇₅	(L/S)				
MEF ₅₀	(L/S)				
MEF ₂₅	(L/S)				

(PV=Predicted Value, MV=Measured Value)

Variables	Before	After	Before	After
	(day 0)	(day 0)	(day 90)	(day 90)

Oxygen Saturation % (SpO₂)

Level of dyspnea (Borg Score)

Level of fatigue (Borg Score)

Total Distance (in meter) Walked In 6 Minute :

The Modified Borg Scale:

SCALE	SEVERITY
0	No Breathlessness At All
0.5	Very Very Slight (Just Noticeable)
1	Very Slight
2	Slight Breathlessness
3	Moderate
4	Somewhat severe
5	Severe Breathlessness
6	
7	Very Severe Breathlessness
8	
9	Very Very Severe (Almost Maximum)
10	Maximum

Hematological variables:

Serum 25(OH)D ng/ml

Serum PTH pg/ml

Serum Ca²⁺ mg/dl

Serum IU/L

Alkaline
phosphat
ase

Serum IU/L

SGPT

Serum mg/dl

Creatini
ne

Fasting mg/dl

blood
glucose

Serum %

HbA1c

Serum (mg/dl)

Choleste
rol

Serum (mg/dl)

TG

Serum (mg/dl)

HDL

Serum (mg/dl)

LDL

Serum (mg/dl)

PO₄³⁻