# Vitamin D status and lung function in children with asthma

Submission date	Recruitment status No longer recruiting	<ul><li>Prospectively registered</li></ul>		
24/03/2016		Protocol		
Registration date	Overall study status Completed	Statistical analysis plan		
31/03/2016		[X] Results		
<b>Last Edited</b> 14/03/2019	Condition category Respiratory	[] Individual participant data		
14/03/2019	Respiratory			

## Plain English summary of protocol

Background and study aims

Asthma is a long-term condition which affects the airways. It can affect people of any age, however in usually is first spotted during childhood. When a person is suffering from asthma, the bronchi (tubes which carry air in and out of the lungs) can become narrowed or swollen (inflammation). This can cause a range of distressing symptoms such as wheezing, chest tightness and breathlessness. In recent years, a number of studies have shown that there may be a link between the level of vitamin D in the blood and how severe asthma symptoms are in children. Vitamin D is an essential vitamin which our bodies produce when sunlight shines on the skin. The aim of this study is to evaluate the vitamin D levels in children with asthma and healthy control group in order to find out whether there is a relationship between vitamin D levels and asthma.

#### Who can participate?

Children aged between 7 and 17 with asthma and healthy children of the same age.

#### What does the study involve?

Children with asthma have a sample of blood taken so that it can be used to test the level of vitamin D in the blood, as well as levels of allergen-spesific IgE (a chemical marker for asthma). These participants also have their lung function tested through a breathing test, which is repeated three times so the most accurate result can be obtained. This involves taking a deep breath in and then blowing into a tube attached to a machine as hard as possible to measure how well the lungs are functioning. Healthy children have a sample of blood taken so that it can be tested for vitamin D levels. The vitamin D levels are then compared between the groups in order to find out if there is a link to asthma. In addition, the severity of asthma symptoms in the asthmatic children are compared to their vitamin D levels.

What are the possible benefits and risks of participating?

Participants who are found to have low levels of vitamin D will benefit from receiving a referral to a specialist in order to treat them. There are no notable risks involved with taking part in the study.

Where is the study run from?
Sisli Hamidiye Etfal Research and Training Hospital (Turkey)

When is the study starting and how long is it expected to run for? September 2011 to June 2013

Who is funding the study?
Sisli Hamidiye Etfal Research and Training Hospital (Turkey)

Who is the main contact?
Dr Sebnem Ozdogan
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# Contact information

## Type(s)

Scientific

#### Contact name

Dr Sebnem Ozdogan

#### Contact details

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# Additional identifiers

Protocol serial number

527

# Study information

#### Scientific Title

Association between vitamin D levels and pulmonary function parameters in children with asthma

#### **Study objectives**

There is a correlation between serum vitamin D levels and pulmonary function in children with asthma.

#### Ethics approval required

Old ethics approval format

#### Ethics approval(s)

Ethics Committee of Sisli Hamidiye Etfal Research and Training Hospital, 19/11/2012, ref: 527

#### Study design

Single-centre case-control study

#### Primary study design

Observational

#### Study type(s)

Diagnostic

## Health condition(s) or problem(s) studied

**Asthma** 

#### **Interventions**

A total of 71 patients between 7 and 17 years of age with diagnosis of asthma will be included in the study as patient group. A total of 77 healthy children who presents for routine physical in pediatrics will be included as a control group.

Asthma group: The investigator will inform the patients and their families about the study. In the first visit: Demographic information such as age, gender, history of hospitalization for asthma attack in the previous year, the parental history of asthma, will be recorded. Each participant's body weight and height will be measured. Blood samples will be obtained from the asthma group to measure serum total IgE levels, allergen-spesific IgE levels (using an inhalant phadiotop panel) and vitamin D levels (If total IgE and allergen specific IgE were measured before, we will use the previous records). Pulmonary function tests will be obtained by a pediatric pulmonologist.

Control group: The investigator will inform the children and their families about the study. After obtaining demographics, only vitamin D levels will be measured.

## Intervention Type

Other

## Primary outcome(s)

- 1. Vitamin D levels are measured using blood testing at the study visit
- 2. Pulmonary function (in asthma patients only) is measured using blood testing for serum total IgE levels at the study visit and correlated to vitamin D levels

# Key secondary outcome(s))

Association between vitamin D levels and asthma clinical features (in asthma patients only) are measured through serum vitamin D testing and pulmonary function tests (spirometry) completed by a by a pediatric pulmonologist at the study visit.

# Completion date

30/06/2013

# **Eligibility**

# Key inclusion criteria

#### Patient inclusion criteria:

- 1. Aged between 7 and 17 years
- 2. Asthma diagnosis
- 3. Followed at the pediatric outpatient pulmonology clinics between December 2012 and March 2013

#### Healthy controls inclusion criteria:

- 1. Aged between 7 and 17 years
- 2. Healthy

#### Participant type(s)

**Patient** 

#### Healthy volunteers allowed

No

#### Age group

Child

## Lower age limit

7 years

#### Upper age limit

17 years

#### Sex

All

#### Key exclusion criteria

- 1. Patients with chronic diseases other than asthma (renal, hepatic, endocrine, metabolic, or neurological disorders)
- 2. Those taking vitamin D supplements, anti-epileptic drugs or systemic steroids=

#### Date of first enrolment

01/11/2012

#### Date of final enrolment

20/03/2013

# Locations

#### Countries of recruitment

Turkmenistan

Türkiye

## Study participating centre Sisli Hamidiye Etfal Research and Training Hospital Istanbul

# Sponsor information

# Organisation

Sisli Hamidiye Etfal Research and Training Hospital

#### **ROR**

https://ror.org/05fmwts39

# Funder(s)

# Funder type

Hospital/treatment centre

#### **Funder Name**

Sisli Hamidiye Etfal Research and Training Hospital

# **Results and Publications**

Individual participant data (IPD) sharing plan

# IPD sharing plan summary

Available on request

# **Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/05/2017	14/03/2019	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes