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Vitamin D status and lung function in children with asthma

Submission date	Recruitment status	[_] Prospectively registered
24/03/2016	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
31/03/2016	Completed	[X] Results
Last Edited	**Condition category**	[_] 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?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Case-control study

Study setting(s)
Hospital

Study type(s)
Diagnostic

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet.

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 demograghics, only vitamin D levels will be measured.

Intervention Type
Other

Primary outcome measure

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

Secondary outcome measures
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.

Overall study start date
30/09/2011

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

Age group
Child

Lower age limit
7 Years

Upper age limit
17 Years

Sex
Both

Target number of participants
148

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
Türkiye
34742

Sponsor information

Organisation
Sisli Hamidiye Etfal Research and Training Hospital

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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/05fmwts39

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Sisli Hamidiye Etfal Research and Training Hospital

Results and Publications

Publication and dissemination plan
Planned publication in a peer reviewed journal.

Intention to publish date
30/04/2016

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