

# Vitamin D deficiency can make acne worse

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| <b>Submission date</b><br>06/10/2015   | <b>Recruitment status</b><br>No longer recruiting                | <input type="checkbox"/> Prospectively registered<br><input checked="" type="checkbox"/> Protocol |
| <b>Registration date</b><br>15/10/2015 | <b>Overall study status</b><br>Completed                         | <input type="checkbox"/> Statistical analysis plan<br><input checked="" type="checkbox"/> Results |
| <b>Last Edited</b><br>07/11/2023       | <b>Condition category</b><br>Skin and Connective Tissue Diseases | <input type="checkbox"/> Individual participant data  |

## Plain English summary of protocol

### Background and study aims

Vitamin D is essential for good health, because it helps our bodies to absorb calcium from the diet. There is a lot of evidence that vitamin D can help protect against many diseases, such as heart disease, bone diseases and cancer. Although vitamins generally come from the diet, the majority of people actually get most of their vitamin D from sunlight. When the sun shines on our skin, a reaction in the body is triggered, producing an active form of vitamin D (known as vitamin D3). Vitamin D plays an important role in the immune system and low levels in the body have been linked to various skin diseases. Acne is a very common skin condition that causes spots to develop on the skin, particularly on the face, back and chest. It is caused by when small oil glands (sebaceous glands) produce too much oil (sebum) which blocks pores and causes inflammation. Recent studies have suggested that vitamin D deficiency may be linked to the development of acne, however the reason why is still unclear. In this study, the levels of vitamin D will be compared in people with and without acne to see if there is a link between acne and vitamin D deficiency. The study will then find out whether taking a vitamin D3 supplement (cholecalciferol) is an effective way to treat acne.

### Who can participate?

Adults between 20 and 35 years with acne, and healthy adults of the same age.

### What does the study involve?

In the first part of the study, the patients with acne and the healthy participants have a blood test so that their vitamin D levels can be measured. In the second part of the study, the acne patients are randomly allocated to one of two groups. Those in the first group take the vitamin D supplement cholecalciferol by mouth every day for two months. Those in the second group take an identical looking placebo (inactive medication) every day for two months. Participants in both groups are examined by experts at the start of the study and then at 2, 4 and 8 weeks in order to judge the severity of their acne.

### What are the possible benefits and risks of participating?

A benefit of taking part in the study is that all participants are able to find out whether they have a vitamin D deficiency, and patients involved in the second part of the study have the change of receiving vitamin D supplements. There are no major risks of participating, although there is a risk of pain or bruising during blood tests.

Where is the study run from?  
Chungnam University Hospital (South Korea)

When is the study starting and how long is it expected to run for?  
November 2014 to February 2015

Who is funding the study?  
Ministry of Health & Welfare (South Korea)

Who is the main contact?  
Dr Seulki Lim

## Contact information

**Type(s)**  
Public

**Contact name**  
Dr Seulki Lim

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282 Munhwa-ro  
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Daejeon  
Korea, South  
35015

## Additional identifiers

**Clinical Trials Information System (CTIS)**  
Nil known

**ClinicalTrials.gov (NCT)**  
Nil known

**Protocol serial number**  
N/A

## Study information

**Scientific Title**  
Functional role of vitamin D in patients with acne

**Study objectives**  
The aim of this study is to determine the effect of vitamin D supplementation on acne.

**Ethics approval required**

Old ethics approval format

### **Ethics approval(s)**

Institutional Review Board of Chungnam National University Hospital, 24/07/2014, ref: CNUH 2014-07-013

### **Study design**

Randomized controlled trial

### **Primary study design**

Interventional

### **Study type(s)**

Treatment

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

Acne

### **Interventions**

Acne patients and healthy controls have a blood test so that their serum 25-hydroxy vitamin D (25(OH)D) concentrations can be measured.

The acne patients were randomly assigned to either a 2 month oral administration of cholecalciferol (one drop of 1000 IU/day, n=20) or an identical-appearing placebo drop (n=19). Any other topical or systemic acne treatments, except for standard washing and moisturizing, were not allowed.

### **Intervention Type**

Supplement

### **Primary outcome(s)**

Serum vitamin D level in patients with acne and healthy controls is measured using blood analysis of 25-hydroxy vitamin D (25(OH)D) concentration at baseline.

### **Key secondary outcome(s)**

1. The severity of acne was assessed using digital photographs and the global acne grading system (GAGS) score at baseline, 2, 4 and 8 weeks
2. Counts of non-inflammatory lesions (comedones) and inflammatory lesions (papules, pustules, and nodules) were made at each visit, and dermatological assessments were performed blind by three independent dermatologists

### **Completion date**

30/04/2015

## **Eligibility**

### **Key inclusion criteria**

1. Adults aged between 20 and 35 years with acne
2. Adults aged between 20 and 35 years without acne (healthy controls)

### **Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

20 years

**Upper age limit**

35 years

**Sex**

All

**Total final enrolment**

160

**Key exclusion criteria**

1. Receiving therapeutic interventions such as acne treatment, systemic corticosteroids, vitamin D supplements
2. Subjects with concomitant inflammatory diseases

**Date of first enrolment**

01/11/2014

**Date of final enrolment**

28/02/2015

## **Locations**

**Countries of recruitment**

Korea, South

**Study participating centre**

**Chungnam University Hospital**

282, Munhwa-ro

Jung-gu

Daejeon

Korea, South

35015

## **Sponsor information**

**Organisation**

Chungnam National University Hospital

**ROR**

<https://ror.org/04353mq94>

**Funder(s)****Funder type**

Government

**Funder Name**

Ministry of Health & Welfare

**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? |
|----------------------------------|---------|--------------|------------|----------------|-----------------|
| <a href="#">Results article</a>  |         | 25/08/2016   | 07/11/2023 | Yes            | No              |
| <a href="#">Protocol (other)</a> |         | 25/08/2016   | 07/11/2023 | No             | No              |