

Vitamin D deficiency can make acne worse

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

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 chance 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

ORCID ID
<https://orcid.org/0000-0002-9907-0628>

Contact details
282 Munhwa-ro
Jung-gu
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 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?
Results article		25/08/2016	07/11/2023	Yes	No
Protocol (other)		25/08/2016	07/11/2023	No	No