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Vitamin D deficiency can make acne worse

Submission date	Recruitment status	[_] Prospectively registered
06/10/2015	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
15/10/2015	Completed	[X] Results
Last Edited	**Condition category**	[_] 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 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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35015

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

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 measure
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.

Secondary outcome measures
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

Overall study start date

01/11/2014

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

Age group
Adult

Lower age limit
20 Years

Upper age limit
35 Years

Sex
Both

Target number of participants
This study includes 80 patients with acne and 80 healthy controls.

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

Sponsor details
282 Munhwa-ro
Jung-gu
Daejeon
Korea, South
35015

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/04353mq94

Funder(s)

Funder type
Government

Funder Name
Ministry of Health & Welfare

Results and Publications

Publication and dissemination plan
Planned submission to the journal PLoS One for publication.

Intention to publish date
31/03/2016

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?
Protocol (other)		25/08/2016	07/11/2023	No	No
Results article		25/08/2016	07/11/2023	Yes	No