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A clinical study on the effects of ω-3 fatty acids on moderate and severe acne and gut microbiota

Submission date
30/08/2022

Recruitment status
No longer recruiting

Registration date
07/09/2022

Overall study status
Completed

Last Edited
03/01/2024

Condition category
Skin and Connective Tissue Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Acne, an inflammatory disease of the follicles of the skin, may induce scars which can be long-lasting and have negative impact on the physical and mental health of the patients. However, its first-line treatment, isotretinoin, can lead to unacceptable side effects, which greatly limits its clinical application. It is very urgent to find new treatments for acne. A previous study showed that a disorder of the gut microbiota (bacteria) occurred in patients with acne. Omega-3 (ω-3) fatty acids have attracted extensive attention due to their strong anti-inflammatory effects and positive effects on gut microbiota. Therefore, the aim of this study is to find out whether ω-3 fatty acids can treat acne vulgaris by regulating gut microbiota and its metabolites.

Who can participate?
Healthy volunteers or patients with moderate and severe acne vulgaris, at least 18 years of age, maximum age 30 years.

What does the study involve?
The healthy volunteers do not receive any treatment. All patients are randomly allocated to oral isotretinoin in combination with (or without) omega-3 (ω-3) fatty acids for 12 weeks. Skin tests are carried out and blood and feces samples are collected at the start of the study and after 12 weeks of treatment.

What are the possible benefits and risks of participating?
Patients could benefit from the treatment and their clinical symptoms may be relieved to some extent. This study may find a new treatment for acne. The main risk comes from the side effects of isotretinoin, such as dry mucous membranes, elevated liver enzymes, dyslipidemia and fetal malformation. If the patient has adverse reactions due to the test drug during the treatment, the researcher should immediately terminate the patient to continue the trial.

Where is the study run from?
Affiliated Hospital of Southwest Medical University (China)

When is the study starting and how long is it expected to run for?
July 2019 to December 2021

Who is funding the study?
1. Joint project of Southwest Medical University and Suining People's Hospital (China)
2. Joint project of Southwest Medical University and Luzhou Science and Technology Bureau (China)
3. Project of Sichuan Provincial Department of Science and Technology (China)
4. National Natural Science Foundation of China (China)
5. Southwest Medical University (China)

Who is the main contact?
Yongqiong Deng, dengyongqiong1@126.com

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Version 1.0

Study information

Scientific Title
A clinical study on the adjuvant treatment of ω-3 fatty acids in moderate and severe acne vulgaris through positive regulation of disordered gut microbiota

Study objectives
ω-3 fatty acids could play a therapeutic role in moderate and severe acne vulgaris patients by regulating gut microbiota

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 03/07/2020, the clinical trial ethics committee of the Affiliated Hospital of Southwest Medical University (No. 25, Taiping Street, Luzhou, 646000, Sichuan Province, China; +86 (0) 8303165273; xnydfyirb@sina.com), ref: KY2020115

Study design
Single-center interventional single-blinded randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Moderate and severe acne vulgaris

Interventions
The healthy volunteers do not receive any treatment. All patients are randomized (using a computational random grouping table made by IBM SPSS Statistics 21.0) to oral isotretinoin in combination with (or without) omega-3 (ω-3) fatty acids for 12 weeks. The ω-3 fatty acids are given at a dose of 2400 mg/d. The isotretinoin is started at the initial doses of 0.5-1.0 mg/ (kg.d), then adjusted according to the drug side effects, and the curative effect is evaluated by the Global Acne Grading System (GAGS). When the GAGS is 19 ~ 30, the dose of isotretinoin is given by 0.5 mg/ (kg.d). If the GAGS >30, the researchers increase the dose of isotretinoin to 1.0 mg/ (kg.d). If the patient's primary skin lesions gradually improve without new skin lesions occurring, the dose of isotretinoin is reduced to 0.5 mg/ (kg.d) by degrees. The collection of samples from the patients is arranged at baseline and after 12 weeks of treatment. The ω- 3 fatty acids are

packed in a sealed package with a unique number. During the whole study, the researcher distributes the drug according to the drug number of each subject, and the drug number shall not be changed.

Intervention Type
Supplement

Primary outcome measure
16s rDNA sequence measured from fresh fecal sample at baseline and after 12 weeks of treatment

Secondary outcome measures
1. Disease severity of acne vulgaris measured using the Global Acne Grading System (GAGS) at baseline and after 12 weeks of treatment
2. The percentage of red area and porphyrins on the front, left and right sides measured respectively using the VISIA-CR™ imaging system at baseline and after 12 weeks of treatment
3. The levels of blood glucose, cholesterol, triglyceride, low-density lipoprotein (LDL) and high-density lipoprotein (HDL) from fasting venous blood measured enzymatically with an automatic analyser at baseline and after 12 weeks of treatment
4. Fasting insulin measured using ELISA at baseline and after 12 weeks of treatment
5. Insulin resistance measured using the homeostasis model assessment of insulin resistance (HOMA-IR) at baseline and after 12 weeks of treatment
6. Serum sample collected for liquid chromatography tandem mass spectrometry (LC-MS/MS) analysis at baseline and after 12 weeks of treatment

Overall study start date
01/07/2019

Completion date
31/12/2021

Eligibility

Key inclusion criteria
1. Patients who meet the criteria for diagnosis and classification of moderate and severe acne vulgaris or healthy volunteers
2. Male or female, at least 18 years of age, maximum age 30 years
3. Body mass index (BMI) 18-25 kg/m^2
4. No isotretinoin and ω-3 fatty acids were taken orally within 6 months
5. No drugs were systematically applied within 6 months
6. Participants who have signed the informed consent

Participant type(s)
Mixed

Age group
Other

Lower age limit
18 Years

Upper age limit
30 Years

Sex
Both

Target number of participants
60

Total final enrolment
46

Key exclusion criteria
1. Participants with other skin diseases.
2. Participants with immune deficiency or other immune diseases
3. Participants with metabolic diseases such as diabetes and hyperlipidemia
4. Participants with tumors and other serious medical diseases
5. Smokers and alcoholics
6. Pregnant and lactating women
7. Participants who had undergone gastrointestinal surgery
8. Participants with the allergic constitution
9. Participants who known to be allergic to isotretinoin and ω-3 fatty acids
10. Participants who refuse to sign the informed consent form

Date of first enrolment
10/07/2020

Date of final enrolment
30/06/2021

Locations

Countries of recruitment
China

Study participating centre
The Affiliated Hospital of Southwest Medical University
Department of Dermatology & STD
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Sponsor information

Organisation
Affiliated Hospital of Southwest Medical University

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Sponsor type
Hospital/treatment centre

Website
http://www.ahswmu.cn

ROR
https://ror.org/0014a0n68

Funder(s)

Funder type
Government

Funder Name
Joint project of Southwest Medical University and Suining People's Hospital (grant no. 2021SNXNYD01, 2021SNXNYD04)

Funder Name
Joint project of Southwest Medical University and Luzhou Science and Technology Bureau (grant no. 2021LZXNYD-Z04)

Funder Name
Department of Science and Technology of Sichuan Province (grant no. 2020YFS0456)

Alternative Name(s)
Sichuan Provincial Department of Science and Technology, Department of Science and Technology of Sichuan Province, Science & Technology Department of Sichuan Province, , SPDST

Funding Body Type
Government organisation

Funding Body Subtype
Local government

Location
China

Funder Name
National Natural Science Foundation of China (grant no. 81970676)

Alternative Name(s)
Chinese National Science Foundation, Natural Science Foundation of China, National Science Foundation of China, NNSF of China, NSF of China, , National Nature Science Foundation of China, Guójiā Zìrán Kēxué Jījīn Wěiyuánhuì, NSFC, NNSF, NNSFC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
China

Funder Name
Southwest Medical University (grant no. 2021ZKMS027/2021ZKMS030)

Alternative Name(s)
, SWMU

Funding Body Type
Government organisation

Funding Body Subtype
Universities (academic only)

Location
China

Results and Publications

Publication and dissemination plan
The researchers plan to publish in high-impact peer-reviewed journals

Intention to publish date

31/12/2022

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are/will be available upon request from Dr Yongqiong Deng (dengyongqiong1@126.com). Individual participant data that underlie the results will be available upon request after publication and ending 12 months after publication. The datasets are stored on spreadsheets and all appropriate requests for appropriate analysis and mechanisms will be considered.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		02/01/2024	03/01/2024	Yes	No