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A study to assess the safety and efficacy of a gel treatment in subjects with acne vulgaris

Submission date
29/06/2024

Recruitment status
No longer recruiting

Registration date
11/11/2024

Overall study status
Completed

Last Edited
11/02/2026

Condition category
Skin and Connective Tissue Diseases

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
This study aims to assess the effectiveness and safety of a gel treatment, in comparison to a placebo gel, applied once daily for 12 weeks in patients with acne vulgaris.

Who can participate?
Patients aged between 9 and 50 years of age suffering from acne vulgaris

What does the study involve?
Participants will be randomly assigned to either the treatment or placebo gel and they will not be made aware of which treatment they have been assigned to. The study will include up to six on-site visits over a duration of 16 weeks. The visits will last 1-2 hours and will include some physical assessments and investigations. Patients will have an assessment of acne symptoms and a collection of height, weight, and vital signs. Patients will also complete a questionnaire which will assess how their condition affects their daily life. Participants will be required to apply the Investigational Product (gel treatment, either active or placebo) themselves, once daily for the duration of the study period.

What are the possible benefits and risks of participating?
In previous studies, the active treatment gel has been shown to be safe and well tolerated and a reduction of acne symptoms was found. This study will help gather further information on the effects of this gel and may offer an alternative treatment for patients suffering from acne vulgaris.
Based on the results from two previous large Phase II studies, the active IMP (N-Acetyl-GED-0507-34-LEVO gel 5% (5 mg/100 mg)), is considered to be safe and well tolerated and there were no significant differences between the proposed pediatric and adult population. In a large randomised double-blind controlled clinical trial (NAC-GED-0507-ACN-01-18), the percentage of patients who had one or more AEs was 19%, 16% and 19% in the NAC-GED 5%, NAC-GED 2% and vehicle groups, respectively. In general, the administration of the IMP may result in some minor side effects such as an allergic or irritant reaction, which may manifest as itching or redness of the skin with papules and blisters. In rare cases, there may be more generalised dermal sensitisation responses, which improve once the treatment stops. Moreover, as the amount to be applied to the skin is relatively small, no systemic side effects are expected. For those

participants who are randomised to receive the vehicle IMP, as their condition will not be treated with an active medication for the duration of the study, their acne symptoms may become worse, stay the same or improve.
With regard to risks associated with pregnancy and breastfeeding, the safety of the study drug for embryos/fetuses is not fully known. Females who are pregnant or breastfeeding or those who plan to become pregnant during the study period will be excluded from enrollment. Additionally, all females of childbearing potential will be required to undertake a pregnancy test and shall also be required to use an acceptable effective contraceptive method throughout the entire study.
Although acne is not a life-threatening condition, it can be a significant source of distress for patients and can be associated with depression, anxiety and poor self-esteem. Patients will be required to complete either a Dermatology Life Quality Index (DLQI) (age 17 and older) or a Children's Dermatology Life Quality Index (C-DLQI) (for 16 years and younger). By completion of these questionnaires, there is a risk that some participants may experience some psychological or emotional stress. Similarly, as there is a chance that participants' acne symptoms may become worse or remain the same during the study, this may also contribute to participants experiencing psychological or emotional stress.
However, participants' health and wellbeing will be closely monitored during the study and will include the collection of all Adverse Events (AEs), Treatment-Emergent Adverse Events (TEAES), Adverse Drug Reactions (ADRs) and Serious Adverse Events (SAEs). Changes from baseline of vital signs and local tolerability plus physical examinations and an assessment of the overall application of site irritation will also be conducted to ensure prompt follow-up with participants if required. Moreover, additional phone calls will be included for all patients aged 9 to < 12 years at week 2 and at week 10 of treatment, to ensure that any local tolerability or safety issues are promptly identified. The Investigator will be asked to promptly fill in the eCRF page relating to the phone contact. In case of safety issues, an immediate automatic notification will be sent to the Data Safety Monitoring Board (DSMB). A DSMB will also be established to undertake periodic risk-benefit assessments during the clinical trial. Participants who complete 12 weeks of treatment will also be eligible to continue treatment with NAC-GED-0507-34-Levo 5% gel in a separate open-label long-term study (GEDACNE-LT).
Participants will be appropriately reimbursed for any travel expenses and will be made fully aware of the commitment required before consenting. At three selected sites in the UK, participants will also have the option to consent to the collection of photographic scar monitoring of which images of the participant's face will be shared: internally (to the attention of PPM Services' collaborators) and/or externally (to the attention of the public and/or health care professionals during any event and/or manifestation whatsoever). This type of assessment has the potential to cause some emotional stress however, information will be provided to participants via a participant information sheet in a way that enables them to clearly understand what is involved in the study, should they consent to take part.
Taking into account these risks and benefits, the performance of the trial can be considered low risk for all ages considered, since the expected benefits appear greater at present than the risks for the volunteers.

Where is the study run from?
LINK Medical Research (UK)

When is the study starting and how long is it expected to run for?
June 2024 to May 2026

Who is funding the study?
PPM Services P.A (Sweden)

Who is the main contact?
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Contact information

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Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
2023-510341-19

Integrated Research Application System (IRAS)
1010206

Central Portfolio Management System (CPMS)
60290

Protocol serial number
NAC-GED-0507-ACN-01-23-B

Study information

Scientific Title
A phase III study to assess the efficacy and safety of N-acetyl-GED-0507-34-LEVO gel 5%, applied once daily for 12 weeks in patients with acne vulgaris (GEDACNE-2)

Acronym
GEDACNE 2

Study objectives
Primary objective:
The objective of the study is to evaluate the efficacy and the safety of 5% N-Acetyl-GED-0507-34-Levo gel, in comparison to the corresponding vehicle gel, applied once daily (OD) for 12 weeks in patients with acne vulgaris.

Secondary objective:
To evaluate the efficacy of 5% N-Acetyl-GED-0507-34-Levo gel in comparison to IMP 2-V after 12 weeks of treatment for a range of parameters on the face and trunk area.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 08/11/2024, London- Hampstead Research Ethics Committee (2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; +44 (0)207 104 8171; hampstead.rec@hra.nhs.uk), ref: 24/LO/0547

Primary study design
Interventional

Study design
Double-blind parallel-group randomized placebo-controlled trial

Study type(s)
Efficacy, Safety

Health condition(s) or problem(s) studied
Acne vulgaris

Interventions
IMP 1 arm: N-Acetyl-GED-0507-34-Levo 5% gel (5 mg/100 mg)
IMP 2/Vehicle arm (V): N-Acetyl-GED-0507-34-Levo

Each patient will apply a bean-sized amount of gel (IMP 1 or IMP 2-V) as a thin film, once daily (OD), to the entire facial skin area and the affected skin areas of the trunk accessible for self-application (i.e., shoulders, upper back, and upper anterior chest). The application is to dry and, cleansed skin, avoiding the eyes, lip region, and mucous membranes. There will be a 12-week treatment period (84 applications) for both IMP 1 and IMP 2-V. Treatment allocation will be on a 1:1 ratio in a blinded manner. The randomisation schedule will be constructed using SAS (Statistical Analysis System, SAS, Cary, NC). Patients who are eligible for enrollment into the trial will be randomised and assigned a randomization/kit number (randomization number = kit number). This randomization/kit number is different from the patient number and will only serve for treatment assignment, not for patient identification. The randomization/kit number will be

recorded in the eCRF and the source documents, thus an allocation is possible at any time. The patients will be randomised at V2/Day 1 by the interactive web response system (IWRS) to ensure study medication assignment according to stratification.

Intervention Type
Drug

Phase
Phase III

Drug/device/biological/vaccine name(s)
N-Acetyl-GED-0507-34-Levo 5% gel [(S)-3-(4-acetamidophenyl)-2-methoxypropanoic acid]

Primary outcome(s)
Efficacy is measured via analysis of the relative change in total lesion count (inflammatory plus noninflammatory) on the face at baseline and Visit 5/Week 12 AND via the proportion of patients with a change in acne severity measured using the Investigators Global Assessment (IGA) at baseline and Visit 5/Week 12.

Key secondary outcome(s)
1. Efficacy is measured via analysis of the absolute change in total lesion count at baseline and Visit 5/Week 12 AND via the percentage of patients who achieve an IGA success over the study duration measured using the Investigators Global Assessment (IGA) at baseline and Visit 5/Week 12.
2. Efficacy will also be measured via patient-reported outcomes using the Dermatology Life Quality Index (DLQI) or the Children's Dermatology Life Quality Index (C-DLQI), scar assessments and photographic scar monitoring (at selected sites only) at baseline and Visit 5/Week 12.

Completion date
31/05/2026

Eligibility

Key inclusion criteria
1. Written informed consent, before any study-related procedure, personally signed and dated by the patient if the patient is ≥18 years old, or signed and dated by the parents or the legal guardian(s) if the patient is ≥ 9 to < 18 years old. An additional informed assent form must be signed by the patient if ≥9 to <18 years old to confirm his willingness to participate in the study. If the patient becomes 18 years of age during the study, the patient must provide written informed consent at that time to continue study participation.
2. Male and female patients aged ≥9 and <50 years.
3. Diagnosis at screening and baseline visits:
3.1. Patients affected by facial acne vulgaris with:
Investigator's Global Assessment (IGA) score:
3.1.1. Equal to 3–4 if the patient is >14 and <50 years old
3.1.2. ≥2 if the patient is ≥9 and ≤14 years old.
3.1.3. Face Inflammatory lesions: ≥20 and ≤100 inflammatory lesions (papules and pustules) and ≤ 1 nodules on the face
3.1.4. Face Non-inflammatory lesions: ≥20 and ≤100 non-inflammatory lesions (open and closed comedones) on the face
3.2. Patients affected also by truncal acne (optional criteria):

3.2.1. The patient has truncal acne on areas of the trunk (shoulders, upper back and upper anterior chest) accessible for the patient's self-application of study medication with a severity grade equal to 2 or 3 on the Physician Global Assessment (PGA) scale.
3.2.2. The patient has a minimum of 20 inflammatory lesions (papules and pustules) and 20 non-inflammatory lesions (open and closed comedones) but no more than 100 non-inflammatory lesion counts on areas of the trunk (shoulders, upper back and upper anterior chest) reachable to patient's self-application of study medication at screening and baseline
4. Patients and their parents/legal guardian(s) (for <18 years old patients) can comprehend the whole nature and purpose of the study, including possible risks and side effects, and are able to cooperate with the Investigator and to comply with the requirements of the entire study
5. Women of childbearing potential must be using an effective contraception method during the entire duration of the study (effective contraception methods are those considered at least "acceptable" according to CTFG Recommendations). A prior stable treatment period is required for the following reliable methods of contraception:
5.1. Hormonal oral, implantable, transdermal, or injectable contraceptives must be stable for at least 6 months before the baseline visit
5.2. A non-hormonal intrauterine device (IUD) must be started at least 2 months before the baseline visit.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
9 Years

Upper age limit
50 Years

Sex
All

Total final enrolment
400

Key exclusion criteria
1. Patients with a known history of acne persistent and unresponsive to topical and/or oral treatments within 6 months before randomisation, patients with generalised or localised acne forms other than acne vulgaris, or patients with acne requiring systemic treatment.
2. Patients with a beard or who intend to grow a beard and/or to perform a facial tattoo during the study or patients with facial hair or facial tattoos that could interfere with study assessments in the investigator's opinion. For patients with truncal acne: body hair, tattoos (or who intend to perform them) on the shoulders, upper back or upper anterior chest accessible to self-application of study medication by the patient that may interfere with the study assessments in the investigator's opinion
3. Patients with other active skin diseases or active skin infections in the facial or truncal region

or any other facial or truncal disease or condition that might interfere with the evaluation of acne or place the patient at unacceptable risk
4. Known or suspected hypersensitivity to any active or inactive ingredient in the study medications. Patients with a history of an allergic reaction or significant sensitivity to the formulations' ingredients
5. Patients who are currently using, will use during the study, or discontinued less than 4 weeks before study baseline the use of prescribed and/or over-the-counter topical therapies for the treatment of acne, including but not limited to: corticosteroids, antibiotics, azelaic acid, benzoyl peroxide, salicylates, α-hydroxy/glycolic acid, any other topical cosmetic therapy for acne and retinoids on the face/trunk
6. Patients who are currently using, will use during the study, or discontinued less than 4 weeks before the study baseline the use of products for facial/truncal application containing glycolic or other acids, masks, washes or soaps containing benzoyl peroxide or salicylic acid, non-mild cleansers or moisturisers containing retinol, salicylic or alpha- or beta-hydroxy acids, facial /truncal procedures such as chemical peel, laser treatment, photodynamic therapy, acne surgery, cryodestruction or chemodestruction, x-ray therapy, intralesional steroids, dermabrasion
7. Patients who are currently using, will use during the study, or discontinued less than 4 weeks before the study baseline phototherapy for the treatment of acne, including but not limited to: UV-A, UV-B, and heliotherapy. Patients who have the need or plan to be exposed to artificial tanning devices or excessive sunlight during the study
8. Patients who are currently using, will use during the study, or discontinued less than 12 weeks before the study baseline the use of systemic therapies for the treatment of acne, including but not limited to: antibiotics and isotretinoin. Other systemic therapy that could affect the patient's acne (i.e., anabolics, lithium, EGRF inhibitors, iodides, systemic corticosteroids - except inhaled corticosteroids or intrathecal corticosteroids - or other immunosuppressants), in the opinion of the investigator
9. Known systemic diseases that can lead to acneiform eruptions:
9.1. Increased androgen production:
9.1.1. Adrenal origin: e.g., Cushing's disease, 21-hydroxylase deficiency
9.1.2. Ovarian origin: e.g., polycystic ovarian syndrome, ovarian hyperthecosis
9.2. Cryptococcosis disseminated
9.3. Dimorphic fungal infections
9.4. Behçet's disease
9.5. Systemic lupus erythematosus (SLE)
10. Participation in the evaluation of any investigational product or device within 24 weeks before the study baseline
11. Patients with underlying uncontrolled or unstable conditions, which, in the Investigator's opinion, could significantly compromise the patient's safety and/or place the patient at an unacceptable risk. Any condition that in the investigator's opinion would make it unsafe for the patient to participate in the study
12. History of alcohol or other substance abuse within one year before screening
13. Patient(s) and parents/legal guardian(s) (if applicable) unable to communicate or cooperate with the investigator due to e.g., language problems, impaired cerebral function, impaired mental conditions
14. Patients who may be unreliable for the study including patients who are unable to return for the scheduled visits
15. Pregnant or breastfeeding women or women of childbearing potential who are planning to become pregnant during the study.
*For all female patients of childbearing potential, pregnancy test result must be negative at screening.

Date of first enrolment

01/01/2025

Date of final enrolment
10/02/2026

Locations

Countries of recruitment
United Kingdom

England

Scotland

France

Italy

Poland

Spain

Study participating centre
Marine Lake Medical Practice
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Orrysdale Road
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CH48 5AA

Study participating centre
Cripps Health Centre
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NG7 2QW

Study participating centre
South Tees Hospitals NHS Foundation Trust
James Cook University Hospital
Marton Road
Middlesbrough
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TS4 3BW

Study participating centre
White Horse Medical Practice
Volunteer Way
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SN7 7YU

Study participating centre
Staploe Medical Centre
Brewhouse Lane
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CB7 5JD

Study participating centre
The Adam Practice
117 Longfleet Road
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BH15 2HX

Study participating centre
FutureMeds Glasgow
99 Firhill Road
Glasgow
Scotland
G20 7BE

Sponsor information

Organisation
PPM Services S.A

Funder(s)

Funder type

Industry

Funder Name
PPM Services S.A

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated and/or analysed during the current study will be published as a supplement to the results publication

IPD sharing plan summary
Published as a supplement to the results publication

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file	version 1.1	17/05/2024	20/03/2025	No	No