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

Submission date
27/06/2024

Recruitment status
Recruiting

Registration date
16/09/2024

Overall study status
Ongoing

Last Edited
02/04/2025

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 with 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 6 on-site visits over 16 weeks. The visits will last for 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. Blood samples will also be collected for safety analysis and patients will also complete a questionnaire which will assess how their condition affects their daily life. Study 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?
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.
In terms of study procedures, blood draws may result in bruising or pain where the sample is taken and in some cases, there is a risk of infection, lightheadedness and/or fainting.
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 years 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, the 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, laboratory tests and local tolerability plus physical examinations and an assessment of the overall application of site irritation will also be conducted as 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).
The study will include up to six on-site visits over a duration of 16 weeks. The visits will last for 1-2 hours and will include some physical assessments and investigations. Participants will be appropriately reimbursed for any travel expenses and will be made fully aware of the commitment required prior to consenting. At one selected site 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 (UK)

Who is the main contact?
Elisha Peers

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
2023-510339-12

IRAS number
1010162

ClinicalTrials.gov number
Nil known

Secondary identifying numbers

NAC-GED-0507-ACN-01-23-A, CPMS 60042

Study information

Scientific Title
A Phase III study to assess efficacy and safety of N-acetyl-GED-0507-34-LEVO gel 5%, applied once daily for 12 weeks in patients with acne vulgaris (GEDACNE-1)

Acronym
GEDACNE 1

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. Please see Protocol section 6.3.2 for further details.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 13/09/2024, London - Hampstead REC (Health Research Authority, 2 Redman Place, Stratford , London, E20 1JQ, United Kingdom; +44 (0)207 104 8345; hampstead.rec@hra.nhs.uk), ref: 24/LO/0536

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

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Safety, Efficacy

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

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 or 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

Pharmaceutical study type(s)
Therapy

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 measure
Efficacy is measured via analysis of the relative change in total lesion count (inflammatory plus noninflammatory) at baseline and Visit 5/Week12 on the face 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.

Secondary outcome measures
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

Overall study start date
21/06/2024

Completion date

31/05/2026

Eligibility

Key inclusion criteria

1. Informed consent obtained: 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 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. Sex and age: 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 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 a truncal acne on areas of the trunk (shoulders, upper back and upper anterior chest) accessible for 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. Full comprehension: 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. Contraception and fertility: 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

Age group

Mixed

Lower age limit

9 Years

Upper age limit
50 Years

Sex
Both

Target number of participants
400

Key exclusion criteria
1. Acne: 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. Beard and facial/body hair, tattoos: 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. Skin diseases: 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. Allergy: 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. Topical therapies: 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. Topical skin care products and procedures: Patients who are currently using, will use during the study, or discontinued less than 4 weeks before 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. Phototherapy: Patients who are currently using, will use during the study, or discontinued less than 4 weeks before study baseline phototherapy for the treatment of acne, including but not limited to: UV-A, UV-B, heliotherapy. Patients who have the need or plan to be exposed to artificial tanning devices or excessive sunlight during the study
8. Systemic therapies: Patients who are currently using, will use during the study, or discontinued less than 12 weeks before study baseline the use of systemic therapies for the treatment of acne, including but not limited to: antibiotics, 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. Investigative studies: Participation in the evaluation of any investigational product or device within 24 weeks before study baseline
11. Diseases: 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. Alcohol and other substance abuse: History of alcohol or other substance abuse within 1 year before screening
13. Communication: 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. Reliability: Patients who may be unreliable for the study including patients who are unable to return for the scheduled visits
15. Pregnancy*: 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
01/11/2024

Date of final enrolment
02/11/2025

Locations

Countries of recruitment
England

France

Italy

Poland

Spain

United Kingdom

Wales

Study participating centre
Albany House Medical Centre
3 Queen Street
Wellingborough

United Kingdom
NN8 4RW

Study participating centre
Chilwell Valley and Meadows Practice
Ranson Road, Beeston
Nottingham
United Kingdom
NG9 6DX

Study participating centre
FutureMeds Birmingham
247-251 Soho Road
Birmingham
United Kingdom
B21 9RY

Study participating centre
FutureMeds Ltd
45 Bridle Rd
Birkenhead
Wirral
United Kingdom
CH62 6EE

Study participating centre
Harrogate and District NHS Foundation Trust
Harrogate District Hospital
Lancaster Park Road
Harrogate
United Kingdom
HG2 7SX

Study participating centre
Heath Lane Surgery
Westfield Avenue
Earl Shilton
Leicester
United Kingdom
LE9 7RT

Study participating centre
Clarence Medical Centre
West Rhyl Primary Care Centre
West Kinmel Street
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United Kingdom
LL18 1DA

Study participating centre
The Practice of Health
31 Barry Road
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Sponsor information

Organisation
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Sponsor type
Industry

Funder(s)

Funder type
Industry

Funder Name
PPM Services S.A

Results and Publications

Publication and dissemination plan

1. Peer-reviewed scientific journals
2. Internal report
3. Submission to regulatory authorities

All information supplied by the Sponsor in connection with this study shall remain the sole property of the Sponsor and is to be considered confidential information. The information obtained during this study may be made available to other physicians who are conducting other clinical studies with the investigational product, if deemed necessary by the Sponsor.

Intention to publish date

31/05/2027

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 2.0	24/01/2025	02/04/2025	No	No