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# Treatment of acne with red light photodynamic therapy

**Submission date**
25/01/2018

**Recruitment status**
No longer recruiting

**Registration date**
01/02/2018

**Overall study status**
Completed

**Last Edited**
23/11/2020

**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 vulgaris is a chronic (long-term) inflammatory skin disease, and is commonly treated with topical or systemic drugs according to the severity of the condition. Retinoids and antibiotic compounds are considered a cornerstone approach in this condition. However, adherence to the treatment and the issue of bacterial resistance undermine the effectiveness in the long term. Photodynamic therapy (PDT) is a treatment that involves the use of light-sensitive medication and a light source to destroy abnormal cells. PDT with aminolevulinic acid (ALA) 20% has been shown to be effective in the treatment of inflammatory acne. Skin tolerability (discomfort) however could be a limiting factor for a widespread use of this approach. A new formulation of ALA 5% in thermosetting gel has recently become available. This formulation allows more convenient application without occlusion and better and more efficient release of the active compound in comparison with traditional ALA formulations like creams or ointments. The aim of this study is to assess the effectiveness of red light PDT using ALA 5% in thermosetting gel in the treatment of mild to moderate acne vulgaris.

Who can participate?
Patients with mild to moderate acne vulgaris with unsatisfactory previous treatments for acne (i. e., topical retinoid, antibiotics)

What does the study involve?
ALA 5% gel is gently applied on the face and rubbed until completely absorbed. After 120 minutes of “incubation” in a dark room, a PDT session is performed (15 minutes under a red light lamp). A second and third PDT session are performed two weeks apart. Acne severity is assessed at the start of the study, after the third PDT session and at a follow-up visit 6 months after the last PDT session.

What are the possible benefits and risks of participating?
Participants may benefit from an effective and well tolerated treatment of their acne without the drawback of poor skin tolerability (retinoids) or progressive lack of effectiveness due to bacterial resistance.

Where is the study run from?
1. Dermatology Clinic University Tor Vergata Rome (Italy)
2. Dermatology Outpatient Service Dr S. Serini (Italy)

When is the study starting and how long is it expected to run for?
February 2017 to January 2018

Who is funding the study?
Cantabria Labs Difa Cooper (Italy)

Who is the main contact?
Dr Massimo Milani
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# Contact information

### Type(s)
Public

### Contact name
Dr Massimo Milani

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# Additional identifiers

### EudraCT/CTIS number

### IRAS number

### ClinicalTrials.gov number

### Secondary identifying numbers
ALAFAST1AC

# Study information

### Scientific Title
The efficacy and safety of "low-dose" 5-aminolevulinic acid (ALA) thermosetting gel photodynamic therapy in the treatment of mild to moderate acne vulgaris

### Study objectives
To evaluate efficacy and tolerability of red light photodynamic therapy (PDT) using a novel 5-aminolevulinic acid in thermosetting gel in the treatment of mild to moderate acne vulgaris.

## Ethics approval required
Old ethics approval format

## Ethics approval(s)
University of Tor Vergata, Rome, Ethical Committee, 22/02/2017

## Study design
Multicenter prospective assessor-blinded non-comparative trial

## Primary study design
Interventional

## Secondary study design
Non randomised study

## Study setting(s)
Hospital

## Study type(s)
Treatment

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

## Health condition(s) or problem(s) studied
Mild to moderate acne vulgaris

## Interventions
ALA 5% gel single application was gently applied 2.5 g on the face and rubbed until complete absorption. After 120 minutes of “incubation” in a dark room, a PDT session (15 minutes under red light lamp with a peak of 630 nm) was performed. A second and a third PDT session were performed two weeks apart. The follow-up visit was performed 6 months after the last PDT session.

## Intervention Type
Device

## Primary outcome measure
Acne severity, assessed using the Global Acne Grading System (GAGS) score according to Doshi (Int J Dermatol 1997 36:416) at baseline, after the third PDT session and at the follow-up visit. A GAG score of 1-18 is considered mild; 19-30, moderate; 31-38, severe; and >39, very severe.

## Secondary outcome measures
Patient-reported local tolerability score (a 4-item grading scale: 0: no skin discomfort; 3: severe skin discomfort) after each PDT session

## Overall study start date
01/02/2017

**Completion date**
15/01/2018

# Eligibility

**Key inclusion criteria**
Mild to moderate acne vulgaris

**Participant type(s)**
Patient

**Age group**
Adult

**Sex**
Both

**Target number of participants**
35

**Total final enrolment**
35

**Key exclusion criteria**
1. Severe acne
2. Skin phototype I
3. Positive history of skin tumor
4. Photodermatosis

**Date of first enrolment**
01/05/2017

**Date of final enrolment**
30/11/2017

# Locations

**Countries of recruitment**
Italy

**Study participating centre**
**Dermatology Clinic University Tor Vergata Rome**
Viale Oxford 1
Rome
Italy
00100

**Study participating centre**
**Dermatology Outpatient Service Dr S. Serini**
Viale Sondrio 2
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# Sponsor information

**Organisation**
Cantabria Labs Difa Cooper

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**Sponsor type**
Industry

**ROR**
https://ror.org/044sr7e96

# Funder(s)

**Funder type**
Industry

**Funder Name**
Cantabria Labs Difa Cooper

# Results and Publications

**Publication and dissemination plan**
The plan is to submit the manuscript to a peer-reviewed international journal.

**Intention to publish date**
01/10/2018

## Individual participant data (IPD) sharing plan

Data regarding outcomes, demographic variables and written informed content are stored in an internal repository and are not freely available.

## IPD sharing plan summary

Not expected to be made available

## Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| Results article | results | 01/02/2019 | 23/11/2020 | Yes | No |