

Treatment of acne with red light photodynamic therapy

Submission date 25/01/2018	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 01/02/2018	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 23/11/2020	Condition category Skin and Connective Tissue Diseases	☐ 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

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Additional identifiers

Protocol serial number

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

Primary study design

Interventional

Study design

Multicenter prospective assessor-blinded non-comparative trial

Study type(s)

Treatment

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(s)

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.

Key secondary outcome(s)

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

Completion date

15/01/2018

Eligibility**Key inclusion criteria**

Mild to moderate acne vulgaris

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

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

Milan

Italy

20100

Sponsor information

Organisation

Cantabria Labs Difa Cooper

ROR

<https://ror.org/044sr7e96>

Funder(s)

Funder type

Industry

Funder Name

Cantabria Labs Difa Cooper

Results and Publications

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