

Treatment of acne with red light photodynamic therapy

Submission date 25/01/2018	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 01/02/2018	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
Last Edited 23/11/2020	Condition category Skin and Connective Tissue Diseases	<input type="checkbox"/> 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

massimomilani1959@gmail.com

Contact information

Type(s)

Public

Contact name

Dr Massimo Milani

Contact details

Via Nota

Milan

Italy

20123

+39 (0)29654231

massimomilani1959@gmail.com

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
Milan
Italy
20100

Sponsor information

Organisation

Cantabria Labs Difa Cooper

Sponsor details

Via Milano 160
Caronno Pertusella
Italy
21042
+39 (0)29659031
massimo.milani@difacooper.com

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