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An assessment of the safety and efficacy of the Acne Scar Treatment Pen to treat facial acne scars

Submission date
05/07/2021

Recruitment status
No longer recruiting

Registration date
13/07/2021

Overall study status
Completed

Last Edited
03/03/2025

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
Scarring is a very common consequence of acne, estimated to occur in up to 95% of acne patients. Scars are the consequence of an impaired wound healing process.

The Acne Scar Treatment Pen was developed by Medical Brands to treat mild ice pick scars in the face. By combining the CROSS method with a state-of-the-art precision applicator that delivers a controlled volume of TCA-ActiveTM instead of using a toothpick with uncontrolled and imprecise volumes, the Acne Scar Treatment Pen is expected to be as effective while safe for its use as an over- the-counter self-care medical device. This clinical investigation aims to assess which concentration of TCA-Active™, 35% or 50% is both the most effective and safest in the treatment of icepick acne scars.

Who can participate?
Healthy males and females aged between 18 and 60 years of age. They must have Fitzpatrick skin types I,II,III, IV and at least 5 icepick acne scars per half face with no more than 30% difference between the 2 sides of the face (this will be determined by clinical examination and with comparable pathology on each half face as judged by the investigator). Subjects must have stopped any topical anti-acne treatments at least 6 months prior to study inclusion. During the study, the participants must refrain from receiving any cosmetic face treatments and must wear sunscreen for the duration of the study.

What does the study involve?
During the baseline visit, participants will provide informed consent, demographics/medical history, allergies/hypersensitivities and prior/concomitant
medications information.
During this visit and the next 6 visits, a clinical evaluation will be made by the dermatologist and photographs of the affected skin to be treated will be taken. The
number and type of facial icepick acne scars will be recorded. The clinician will apply the treatment to the icepick acne scars of the participants. Following this,
patient pain evaluations will be measured. CGI and PGI scores will also be collected.

Finally, a prevention cream (sunscreen) will be dispensed, and participants will be given instructions for its use.
During only the baseline and final follow up visit, participants will be given a questionnaire concerning Quality of Life to fill out.
In the study follow-up visit (D135), in addition to the aforementioned measures, a patient satisfaction evaluation will be made.

What are the possible benefits and risks of participating?
Benefits of participation: Treatment of icepick acne scars on the face with a state of the art precision applicator which is expected to be effective and safe for use as an over-the-counter self-care medical device. Resolution of icepick acne scars is expected to have a positive impact on the quality of life of the individuals.
Risks of participation: Potential side effects after application of the formulation may include slight burning, stinging and/or itching sensation during the first few minutes, redness/irritation, and temporary hypo- or hyperpigmentation (for a few weeks). Complications are infrequent. It is extremely rare that a permanent mark or scar occurs. In rare cases, a cold sore infection can be activated. Reactive hyperpigmentation may occur in people with darker skin tones (or as a result of unprotected sun exposure during the 6 weeks after the treatment). Redness of the skin is a normal reaction after the treatment however, a general practitioner should be consulted if this redness persists for 3 weeks after the treatment.

Where is the study run from?
The clinical investigation will be run in a dermatology clinic located in Poland.

When is the study starting and how long is it expected to run for?
April 2021 to November 2022

Who is funding the study?
The study is funded by Medical Brands BV. (Netherlands)

Who is the main contact?
Erica Brusà, qara@medicalbrands.com

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
21E0262 / MB-AST20-203

Study information

Scientific Title
Evaluation of the efficacy and safety of the acne scar treatment pen in the treatment of ice pick acne scars on the face

Study objectives
Current study hypothesis as of 04/02/2022:
Principal aim:
Determine optimal TCA-Active™ concentration by comparing the efficacy of 35%, and 50% TCA-Active™ in the treatment of ice pick acne scars, when administered by patients under the supervision of a clinician.

Secondary aims:
1. Determine the number of cycles required to achieve treatment efficacy
2. Determine the impact of ice pick acne scars on the quality of life of subjects before and after treatment
3. Evaluate visual changes in ice pick acne scars over treatment cycles: number and depth of scars, scar color changes, duration of color changes and number of lesions with scarring due to TCA-Active™ treatment
4. Evaluate patient's pain tolerance during treatment and patient's satisfaction
5. Evaluate the safety of 35% and 50% TCA-Active™ in the treatment of ice pick acne scars

Previous study hypothesis:
Principal aim:
Determine optimal TCA-Active™ concentration by comparing the efficacy of 35%, and 50% TCA-Active™ in the treatment of ice pick acne scars, when administered by a clinician

Secondary aims:
1. Determine the number of cycles required to achieve treatment efficacy
2. Determine the impact of ice pick acne scars on the quality of life of subjects before and after treatment
3. Evaluate visual changes in ice pick acne scars over treatment cycles: number and depth of scars, scar color changes, duration of color changes and number of lesions with scarring due to TCA-Active™ treatment
4. Evaluate patient's pain tolerance during treatment and patient's satisfaction
5. Evaluate the safety of 35% and 50% TCA-Active™ in the treatment of ice pick acne scars

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 15/06/2021, Bioethical Committee at the Regional Medical Chamber in Gdańsk (ul. Śniadeckich 33, 80-204 Gdańsk, III piętro, pokój nr 407, Poland; +31 58 524 32 50; bioetyka@komisjabioetyczna.pl), ref: KB--906

Study design
Double-blinded within-subject (split face) placebo-controlled randomized clinical trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
GP practice

Study type(s)
Treatment

Participant information sheet
No participant information sheet available

Health condition(s) or problem(s) studied
Ice-pick acne scars

Interventions
A variation of trichloroacetic (TCA) chemical peeling, called Chemical Reconstruction of Skin Scars (CROSS) method, which involves local serial application of relatively high concentration TCA (50-100%) to ice pick skin scars using a sharpened wooden applicator, was found to decrease depth of the scars, improve overall appearance and reduce the risk of damaging adjacent normal skin (Lee et al. 2002). The Acne Scar Treatment Pen was developed by Medical Brands to treat mild ice pick scars in the face. By combining the CROSS method with a state-of-the-art precision applicator that delivers a controlled volume of TCA-Active™ instead of using a toothpick with uncontrolled and imprecise volumes, the Acne Scar Treatment Pen is expected to be as effective while safe for its use as an over-the-counter self-care medical device.

66 participants will be randomly assigned to receive either the 35% TCA-Active™ Acne Scar Treatment or the 50% TCA-Active™ Acne Scar Treatment on one hemi-face and the 0% TCA-Active™ comparator on the opposite hemi-face over the course of an 18-week period. The clinical investigation will be double-blinded.

Photographs will be taken every visit, and before and after treatment will be evaluated by a second clinician.

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
35% TCA-Active™ Acne Scar Treatment Pen, 50% TCA-Active™ Acne Scar Treatment Pen

Primary outcome measure
Acne scarring measured using the Clinician Global Impression (CGI) scale of improvement at baseline and 18 weeks

Secondary outcome measures
1. Impact of icepick acne scars on the quality of life at baseline and 18 weeks measured using a novel questionnaire
2. Visual changes in icepick acne scars after each treatment cycle (Baseline, D21, D42, D63, D84, D105, 135) measured by the number and type (superficial, shallow or deep) of ice pick acne scars by clinician evaluation
3. Scar color changes (hypopigmentation, hyperpigmentation, or no changes) and their duration measured by clinician evaluation at baseline, Day 21, Day 42, Day 63, Day 84, Day 105, Day 135 (Equivalent to clinic visits 1, 3, 4, 5, 6, 7 and 8).
4. Disappearance of color changes before the consecutive treatment and also by the end of the follow-up period (D135), assessed on a yes or no criteria.
5. Number of lesions with scarring, assessed by counting observations by clinician evaluation at baseline, Day 21, Day 42, Day 63, Day 84, Day 105, Day 135 (Equivalent to clinic visits 1, 3, 4, 5, 6, 7 and 8).
6. Patient Global Impression (PGI) of improvement of acne scars between baseline and final treatment assessed at baseline, D21, D42, D63, D84 and D105

Usability Endpoints:
7. The patient's evaluation of pain/tolerance during the treatment assessed as their subjective evaluation of pain on a Likert scale. The patient's subjective evaluation of pain acceptability during treatment (Likert scale) will also be assessed (baseline, D21, D42, D63, D84 and D105)
8. Patient satisfaction with the overall results of the treatment will be assessed on a Likert scale (assessed at baseline, D21, D42, D63, D84 and D105)
9. Patient satisfaction with the number of treatments required, assessed on a Likert scale (assessed at baseline, D21, D42, D63, D84 and D105)
10. Patients' opinion on whether the product meets their expectations and whether they would recommend it, both assessed on a Likert scale (assessed at baseline, D21, D42, D63, D84 and D105)

Overall study start date
21/04/2021

Completion date
01/11/2022

Eligibility

Key inclusion criteria
1. Healthy subject
2. Male or female
3. Written informed consent must be obtained from the subject

4. Age between 18 and 60 years
5. Phototype: Fitzpatrick skin types I, II, III, IV
6. Subjects with at least five icepick acne scars per hemiface, and with no more than 30% difference between the two sides of the face, as determined by clinical examination and with comparable pathology on each hemiface as judged by the Investigator
7. Subject having stopped any topical anti-acne treatment since at least 6 months before inclusion
8. Willing to refrain from receiving cosmetic face treatments for the duration of the study
9. Willing to use sunscreen for the duration of the study
10. Female subjects of childbearing potential should use an accepted contraceptive regimen since at least 12 weeks before the beginning of the study, during all the study and at least 1 month after the study end

Participant type(s)
Healthy volunteer

Age group
Adult

Lower age limit
18 Years

Upper age limit
60 Years

Sex
Both

Target number of participants
66

Key exclusion criteria
1. Subject considered by the Investigator likely to be non-compliant with the protocol
2. Patient enrolled in another clinical trial during the test period
3. Woman being pregnant, nursing or planning a pregnancy during the course of this study
4. Subject having a known allergy to one of the constituents of the tested products
5. Patient suffering from serious or progressive diseases (to investigator's discretion), including but not limited to diabetes, peripheral circulatory disease, HIV, immunosuppressive pathology
6. Subject with cutaneous pathology on studied zone, including but not limited to acne, rosacea, angioma, dermatitis, herpes labialis
7. People who were treated with tretinoin within 6 months prior to treatment in this study
8. History of skin tightening or injectable filler of any type within the last year
9. History of facial laser treatment, including ablative and non-ablative resurfacing laser treatments and rejuvenation laser treatments in the last 6 months
10. History of cosmetic treatments with neurotoxins within the last 3 months
11. History of chemical peel or dermabrasion of face and neck within the last 4 weeks
12. History of keloid formation
13. History of hyperpigmentation
14. Fitzpatrick skin types V and VI
15. Prior poor reaction to a chemical peel
16. Subject who was abroad in a country with a higher incidence rate of Covid-19 than Poland,

within 14 days before the beginning of the study.
17. Subject presenting following symptoms: cough, shortness of breath, elevated body temperature – equal and above 37.5°C
18. Subject who have had contact with any person infected with COVID-19 within 10 days before the beginning of the study
19. Subject who are currently home quarantined, as recommended by the Sanitary Inspection

Date of first enrolment
25/09/2021

Date of final enrolment
30/08/2022

Locations

Countries of recruitment
Poland

Study participating centre
Private Practice
ul.Armii Krajowej 11/12
Malbork
Poland
82-210

Sponsor information

Organisation
Medical Brands B.V.

Sponsor details
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Sponsor type
Industry

Funder(s)

Funder type

Industry

Funder Name
Medical Brands B.V.

Results and Publications

Publication and dissemination plan
Clinical Study Report

Intention to publish date
01/01/2023

Individual participant data (IPD) sharing plan
All data generated or analysed during this study will be included in the subsequent results publication

IPD sharing plan summary
Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file	version 3.0	12/03/2021	04/08/2021	No	No