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How Does an Over the Counter Topical called MEBO Scar™ Cosmetically Improve Skin Scars?

Submission date
04/06/2018

Recruitment status
No longer recruiting

Registration date
07/06/2018

Overall study status
Completed

Last Edited
14/07/2023

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
A scar is a natural part of healing. Most people produce fine, thin scars but this can depend on a number of factors. It is thought that a long time for wound healing and skin closure can cause thicker, more raised scars. These unsatisfactory scars are often itchy, painful and cause distress to the sufferers.
This study aims to investigate how the topical application (surface application) of an over the counter cream called MEBO Scar™ cosmetically improves skin scarring and to determine what changes occur in the new scar tissue and cells.

Who can participate?
Healthy volunteers aged over 18 years

What does the study involve?
Participants undergo an 'initial study appointment' (Day 0) where they receive a punch biopsy to create a scar on both upper inner arms. Two weeks later they are asked to apply a topical cream to each of the scars during the study period. During this period they are seen on a fortnightly basis where photographic images are taken of the scars at each visit along with other measurements looking at properties of the scar. Each participant also keeps a diary of how the scar changes over time.
Participants may be in the study for 4 weeks or up to 16 weeks, depending on which group they are allocated to (at random). At the final appointment the scars are biopsied so that they can be evaluated in the lab for further analysis of the effects of both topicals. At that point the participant can leave the trial.
We aim to offer flexible appointments (i.e. early or late appointments). Each visit lasts approximately 30-60 minutes. At the end of the trial all the data is analysed and will answer the question of whether MEBO ScarTM can improve cosmetic scarring.

What are the possible benefits and risks of participating?
There are no direct benefits to participants in this study. Participants are carefully screened so that risks to them taking part (i.e. allergies to any of the topicals or local anaesthetic/dressings) are minimised. They are however left with a scar, which may take time to fade.

Where is the study run from?
Manchester University NHS Foundation Trust (UK)

When is the study starting and how long is it expected to run for?
January 2016 to May 2017

Who is funding the study?
Julphar Gulf, Pharmaceutical Industries (UAE)

Who is the main contact?
Dr Rubinder Basson (scientific)
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
Ethical committee UREC ref 16098

Study information

Scientific Title
Role of MEBO ScarTM cream in enhancing the appearance of cosmetic scars

Study objectives
To evaluate the scar cosmetic appearance - that scars treated with Meboscar TM will have a more improved appearance compared to a positive control (scars treated with Kelo-coteTM)

Ethics approval required
Old ethics approval format

Ethics approval(s)
University of Manchester Ethics Committee 4 UREC, 21/07/2016, ref: 16098

Study design
Interventional randomised blinded single centre design

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
See additional files

Health condition(s) or problem(s) studied
Cosmetic skin scarring

Interventions
Participants are screened and allocated into four groups. Each group represents a time point (4, 8, 12, 16 weeks). Participants receive 5 mm punch biopsies to both upper inner arms to create the scar. They are independently randomised as to which arm should receive either treatment or positive control topicals.
Treatment: MeboscarTM
Control: Kelo-coteTM

Participants apply both topicals according to instructions, (one to each scar, with arms independently randomised by a medical statistician at the University of Manchester). Depending on which group they are in, receive their final biopsy (of the scars) at this time point where they exit the trial.
Topicals are applied from two weeks after the scar is created (on day 0), and up until the point that participant exits the trial (at 4, 8, 12, or 16 weeks).
Topicals are applied twice daily, massaged into the scar for a period of 2 minutes.
Non-invasive measurements are taken on a fortnightly basis for each participants' duration of the trial.
Final scar biopsies are used for histological, gene and protein analysis.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
-

Primary outcome measure
Skin/scar hydration and trans-epidermal water loss is measured using the Dermalab combo (Cortex technologies, Denmark), validated by IHC of hyaluronic acid and qPCR of HYAL 1 and HAS 1.
Colour is measured using the Dermalab combo colour probe (Cortex technologies, Denmark)
Pigmentation is measured using SIAscopy (Medex Health, Canada) - IHC for Melan A and Masson fontana to look for pigmentation
Erythema is measured using Dermalab combo colour probe (Cortex technologies, Denmark), and SIAscropy (Medx Health, Canada); mast cell tryptase staining
Blood flow is measured using FLPI-2 (Moor Instruments, UK), and OCT (Michelson Diagnostics, UK)
Elasticity is measured using Dermalab combo elasticity probe (Cortex Technologies, Denmark), validated by IHC stains for elastin, and fibronectin, with qPCR of elastin and fibronectin.
Collagen is measured using SIAscopy (Medx Health, Canada) and validated by IHC staining for Collagen I and III, and Herovici staining, and qPCR for COL I and III.
H&E staining is also done on all samples to look at skin/scar thickness and structure.
Transdermal delivery of the topical is also assessed using HPLC and Raman spectroscopy.

All of the above are measured for normal skin (day 0) and at weeks 4, 8, 12 and 16.

Secondary outcome measures
Pain, itching and redness are evaluated by the patient using a numerical value out of 10 in a daily diary.

Overall study start date
04/01/2016

Completion date
31/05/2017

Eligibility

Key inclusion criteria
1. Male or female over 18 years old
2. Between 40-150kg (BMI 20-35)
3. Able to understand study requirements and provide written consent

Participant type(s)
Healthy volunteer

Age group

Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
40

Key exclusion criteria
1. Participants who do not give consent to take part in the study
2. Any subject who in the opinion of the investigator is unable to fully understand the requirements of the trial (for example due to a language barrier), consent or is unable to return for follow-up visits and complete the trial
3. Known allergy to any components of the topical formulation
4. Individuals less than 18 years of age will be excluded from the study
5. Individuals who have a history or evidence of keloid scarring or fibrotic disorders (self reported or determined by physical examination)
6. Participants who are pregnant or are planning to conceive in the next 3 months
7. Participants with a chronic or active skin disorder considered to adversely affect the scar healing by the investigator
8. Participants with any likely healing impairment due to a significant medical condition such as renal, hepatic, haematological, neurological or immune disease, including:
9. Rheumatoid arthritis
10. Chronic renal impairment
11. Diabetes Mellitus
12. Significant hepatic impairment
13. Inadequately or uncontrolled congestive heart failure
14. Malignancy – diagnosed or treated within the past 5 years
15. Immunosuppressive, radiation or chemotherapy within the last three month
16. Participants who are receiving anticoagulant therapy, systemic steroids, hormone replacement therapy or any investigational drugs, or have taken any in the previous month prior to Day 0
17. Participants who have evidence of drug abuse
18. Participants who have had or are known to have serum hepatitis or are carriers of hepatitis B surface antigen, hepatitis B core antibodies or hepatitis C antibodies (previous vaccination against hepatitis B and C is not excluded)
19. Participants who have previously had a positive result to the HIV antibody test, or admit to belong to a high risk group
20. Participants who have been involved in other studies in the past two months prior to Day 0 must discuss the exact details of the previous studies prior to a decision being made of eligibility for inclusion in this trial
21. Exclude participants who are allergic to other amide local anaesthetics
22. Previous MRSA colonisation or infection

Date of first enrolment
01/08/2016

Date of final enrolment

01/04/2017

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Manchester University NHS Foundation Trust
Manchester
United Kingdom
M23 9LT

Sponsor information

Organisation
University of Manchester

Sponsor details
Stopford Building
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Sponsor type
University/education

ROR
https://ror.org/027m9bs27

Funder(s)

Funder type
Industry

Funder Name
Partially funded by Julphar Gulf, Pharmaceutical Industries (UAE)

Results and Publications

Publication and dissemination plan
Planned publication in high-impact peer reviewed journal.

Intention to publish date
01/12/2018

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Dr Rubinder Basson, rubinder.basson@postgrad.manchester.ac.uk

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version v1	06/06/2018	02/04/2019	No	Yes
Results article		01/02/2019	14/07/2023	Yes	No