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The role of an over the counter topical containing green tea extract in scarring

Submission date
03/07/2018

Recruitment status
No longer recruiting

Registration date
16/07/2018

Overall study status
Completed

Last Edited
03/08/2021

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.
The antioxidant properties and health benefits of green tea, Camellia sinensis, a popular beverage, have been known for centuries and used in traditional Chinese medicine. A component of green tea has been shown to influence a range of areas including cancer, inflammation, photo protection, anti-aging and wound healing.
This study aims to investigate how the topical application of the green tea cosmetically improves skin scarring and to determine what changes occur in the new scar tissue and cells. Additionally, we would like to identify if and how this topical treatment can reduce the symptoms of scarring and improve the cosmetic quality of skin scarring by its moisturising properties.

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. Depending upon group allocation, two groups will commence immediate application of the topical formulations around the wound site and 5 groups will apply the topicals two weeks after a scar has formed. During this period they are seen on a weekly 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 1 week or up to 8 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 completes the trial.
We aim to offer flexible appointments (i.e. early or late appointments). Each visit lasts approximately 30-60 minutes.

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?
December 2015 to May 2018

Who is funding the study?
Combination - Integra and gift donation

Who is the main contact?
Sara Ud-Din (scientific)
sara.ud-din@manchester.ac.uk

Contact information

Type(s)
Scientific

Contact name
Miss Sara Ud-Din

ORCID ID
https://orcid.org/0000-0002-9791-1403

Contact details
Plastic and Reconstructive Surgery Research
Division of Musculoskeletal and Dermatological Sceiences
Manchester Academic Health Science Centre
University of Manchester
Stopford Building
Oxford Road
Manchester
United Kingdom
M139PL

Additional identifiers

Protocol serial number
Protocol version 7 09.05.2017. University Research Ethics Committee 4 Reference 14333

Study information

Scientific Title
The role of an over the counter topical containing camellia sinensis in the cosmetic management of skin scars

Study objectives
To evaluate the role of topical application of camellia sinensis in scar cosmetic appearance against a placebo

Ethics approval required
Old ethics approval format

Ethics approval(s)
University of Manchester Ethics Committee 4 Reference 14333
Date of approval: 02/10/14

Study design
Interventional randomised controlled blinded single centre

Primary study design
Interventional

Study type(s)
Treatment

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

Interventions
Participants are screened and allocated into seven groups. Each group represents a time point (1,2,3,4,5,6,8 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 placebo topicals.
Treatment: Camellia Sinensis (Green Tea extract)
Placebo: Same base as treatment topical but no active ingredient

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 then complete the trial.

Topicals are applied from two weeks after the scar is created for 5 of the groups and immediately for 2 of the groups (on day 0), and up until the point that participant exits the trial (at 1,2,3,4,5,6,8 weeks).

Topicals are applied twice daily, massaged into the scar for a period of 2 minutes.
Non-invasive measurements are taken on a weekly basis for each participants' duration of the trial.
Final scar biopsies are used for histological, gene and protein analysis.

Intervention Type
Supplement

Primary outcome(s)

Scar 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 SIAscopy (Medx Health, Canada); mast cell tryptase and chymase staining
Blood flow is measured using FLPI-2 (Moor Instruments, UK), and OCT (Michelson Diagnostics, UK), ultrasound (Cortex Technologies, Denmark) measures skin thickness.
Elasticity is measured using Dermalab combo elasticity probe (Cortex Technologies, Denmark), validated by IHC stains for elastin, and fibronectin.
Collagen is measured using SIAscopy (Medx Health, Canada) and validated by IHC staining for Collagen I and III, and Herovici staining.
H&E staining is performed on all samples to look at scar morphology.
RNA sequencing and QRT-PCR performed to validate IHC analyses.
All of the above measurements were taken on a weekly basis through the duration of the trial.

All of the above are measured for normal skin (day 0) and at weeks 1,2,3,4,5,6,8.

Key secondary outcome(s))
Symptom scoring including pain, itching and redness are evaluated by the patient using a numerical value out of 10 in a daily diary.

Completion date
02/10/2019

Eligibility

Key inclusion criteria
1. Aged 16 years or older
2. Able to fully understand study requirements and attend all follow-up visits (in the opinion of the investigator)
3. Weigh between 40 and 150 kg with a body mass index 20-35 kg/m² (as described in the Quetelet's index – weight (kg)/height² (m))

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Total final enrolment
62

Key exclusion criteria

1. Known allergy to any components of the topical formulation
2. History or evidence of keloid scarring or fibrotic disorders (self reported or determined by physical examination)
3. Pregnant or planning to conceive within the next 3 months
4. Chronic or active skin disorder considered to adversely affect the scar healing by the investigator
5. Likely healing impairment due to a significant medical condition such as renal, hepatic, haematological, neurological or immune disease, including rheumatoid arthritis, chronic renal impairment, diabetes mellitus, significant hepatic impairment, inadequately or uncontrolled congestive heart failure, malignancy (diagnosed or treated within the past 5 years) or immunosuppressive, radiation or chemotherapy within the last three months.
6. Receiving anticoagulant therapy, systemic steroids, hormone replacement therapy or any investigational drugs, or have taken any in the previous month prior to Day 0
7. Evidence of drug abuse
8. 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 or C is not excluded)
9. Previously had a positive result to the HIV antibody test, or admit to belong in a high risk group
10. Allergic to other amide local anaesthetics

Subjects 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.

Date of first enrolment
22/12/2015

Date of final enrolment
16/08/2017

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Manchester University NHS Foundation Trust
Wythenshawe Hospital
Southmoor Road
Manchester
United Kingdom
M239LT

Sponsor information

Organisation
University of Manchester

ROR
https://ror.org/027m9bs27

Funder(s)

Funder type
Not defined

Funder Name
Combination - Integra UK and gift donation

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Sara Ud-Din, sara.ud-din@manchester.ac.uk

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		01/08/2019	03/08/2021	Yes	No