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Do resident microorganisms on human skin affect the sunburn response?

Submission date	Recruitment status	[_] Prospectively registered
05/10/2022	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
19/10/2022	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
07/07/2025	Skin and Connective Tissue Diseases	[X] Record updated in last year

Plain English summary of protocol

Background and study aims

The surface of the skin is colonised with an abundance of microorganisms, collectively termed the skin microbiota. These microorganisms play a significant role in inhibiting the colonisation and activity of potentially dangerous microorganisms, educating the skin immune system, and even contribute to the development of normal skin structure. During the whole life span of a human, skin cells and skin microorganisms are exposed to the external environment, including ultraviolet radiation (UVR) in sunlight. The effects of UVR on skin cells has been well studied but the role of the skin microbiota in modulating the response of human skin to sunlight is unknown. Since skin microorganisms are important for skin health, it is important to understand their impact on the skin's response to UVR exposure. Previous research has shown that microorganisms normally found on human skin have different UVR sensitivity and some species may absorb UVR. Certain bacteria produce UVR-inducible factors that influence the UVR response of skin cells grown in the laboratory. The aim of this study is to investigate whether reducing the skin microbiota will impact on UVR-induced effects on human skin such as inflammation (sunburn), cell proliferation and DNA damage.

Who can participate?

Healthy white Caucasian adults of any gender aged 18-40 years

What does the study involve?

The study involves two visits to the Photobiology Unit at Salford Royal Hospital on consecutive days, exposure of the upper back to ultraviolet radiation, and skin biopsies (tissue samples). Please see the Participant Information Sheet for more information.

What are the possible benefits and risks of participating?

The researchers do not expect any individual benefits from participating but the findings from this research could help to show the role of the normal skin microbiota and potentially lead to a better understanding of UVR-related skin disorders (e.g. photosensitivity). The study involves skin biopsies which will leave small permanent scars and there is a low risk of skin infection following the procedure.

Where is the study run from?
Salford Royal Hospital (UK)

When is the study starting and how long is it expected to run for?
February 2020 to December 2023

Who is funding the study?
The Biotechnology and Biological Sciences Research Council (BBSRC) (UK)

Who is the main contact?
Dr Mark Farrar, mark.farrar@manchester.ac.uk

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
317956

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
CPMS 53746, IRAS 317956

Study information

Scientific Title
A role for the commensal microbiota in the response of human skin to ultraviolet radiation

Study objectives
It is hypothesised that the presence of commensal skin microorganisms modulates the responses of human skin to ultraviolet radiation.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 23/06/2022, University of Manchester Research Ethics Committee 2 (Research Governance, Ethics and Integrity, 2nd Floor Christie Building, The University of Manchester, Oxford Road, Manchester, M13 9PL, UK; Tel: not available; research.ethics@manchester.ac.uk), ref: 2022-12972

Study design
Non-randomized; Interventional; Design type: Prevention, Other

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Hospital, University/medical school/dental school

Study type(s)
Other

Participant information sheet
See study outputs table

Health condition(s) or problem(s) studied
Dermatology

Interventions
Previous laboratory research has shown that skin bacteria are able to influence the response of skin cells to UVR, and that cleaning forearm skin with 70% ethanol (as commonly found in anti-bacterial hand cleansers) is effective in reducing the number of skin microorganisms with the maximum reduction reached approximately 2 hours after cleaning and re-establishment after around 6 hours. This study will examine how skin bacteria influence the response of human upper back skin (an area with a greater abundance of bacteria) to UVR in vivo, and the effect of UVR on these bacteria. To achieve this the researchers will first determine the extent of removal of skin bacteria on the upper back following cleaning with 70% ethanol (preliminary study) in n = 6 volunteers. Following this, the main study (n = 10) will explore what effect skin bacteria have on the UVR response of human skin by comparing UVR responses on ethanol-cleaned (at the post-cleaning time point giving the maximum reduction in bacteria as determined in the preliminary study) and uncleaned skin, and by quantifying the bacterial population on skin before and after UVR exposure. Study procedures are as follows:

PRELIMINARY STUDY (completed in a single day in the Stopford Building, University of Manchester or Photobiology Unit, Salford Royal Hospital)
1. Eligibility check and informed consent
2. Demographic data collected, baseline assessments (height, weight, skin colour, skin typing)
3. Skin swab taken
4. Skin (20 x 10cm area) cleaned using 70% ethanol and sterile cotton pads
5. Skin swab taken immediately (approx. 2 min) after cleaning
6. Further skin swabs taken 1h and 2h after cleaning

MAIN STUDY (undertaken in the Photobiology Unit at Salford Royal Hospital)

Visit 1 (Day 1)
1. Eligibility check and informed consent
2. Demographic data collected, baseline assessments (height, weight, skin colour, skin typing)
3. Skin swab is taken from the left side of the upper back
4. Right side of the upper back (20 x 10 cm area) is cleaned using 70% ethanol and sterile cotton pads
5. UVR dose series applied to each side of the upper back (time between steps 4 and 5 determined from the preliminary study)
6. Single low-dose UVR exposure to 6x6 cm area on the left upper back
7. Skin swab is taken from 6x6 cm exposed area of the left upper back

Visit 2 (Day 2)
1. Skin swab is taken from 6 x 6 cm exposed area of the left upper back
2. UVR-erythema (redness) dose-response measured by spectrophotometry
3. A small area (approx. 5 x 5 cm) of the right upper back cleaned using 70% ethanol and sterile cotton pads
4. Single UVR exposure to a 1 cm diameter area within the 5 x 5 cm cleaned area (dose equal to the highest dose in the dose series given on Day 1; time between steps 3 and 4 determined from

the preliminary study) and to a 1cm diameter area on the uncleaned left upper back
5. 5 mm punch biopsy is taken immediately from each of the UVR exposure sites in step 4
6. Further 5 mm punch biopsies taken from (i) the site of the highest dose in the UVR dose series given on Day 1 on both the left (uncleaned) and right (cleaned) side of the upper back, and (ii) an unexposed site on both the left and right side of the upper back.

Visit 3 (Days 9-12)
1. Removal of stitches from biopsy sites

Intervention Type
Other

Primary outcome measure
UVR-induced erythema assessed visually (minimal erythema dose) and objectively by spectrophotometry at 24 hours

Secondary outcome measures
1. Markers of inflammation, DNA damage, apoptosis, and cell proliferation measured by immunofluorescent staining at baseline and 24 hours
2. Density and diversity of skin microbiota measured by 16S rRNA sequencing at baseline and 24 hours

Overall study start date
01/02/2020

Completion date
31/12/2023

Eligibility

Key inclusion criteria
1. Healthy adults of any gender aged 18-40 years
2. White Caucasian (Fitzpatrick skin type I-III)
3. Able to understand and meet study requirements, and provide written informed consent

Participant type(s)
Healthy volunteer

Age group
Adult

Lower age limit
18 Years

Upper age limit
40 Years

Sex
Both

Target number of participants
Planned Sample Size: 16; UK Sample Size: 16

Total final enrolment
16

Key exclusion criteria
1. Skin sensitivity/allergy to alcohol-based skin preparations
2. Existing significant (moderate-severe) skin disease such as eczema, xerosis (dry skin), psoriasis
3. Use of antimicrobial medications in the last 3 months
4. Sunbathing/sunbed use/phototherapy in the last 3 months
5. Currently participating, or have recently participated (within the last month) in other research
6. Unable to meet the requirements for participating in the study

Additional exclusions for the main study:
1. History of photosensitivity disorder or skin cancer
2. History of bleeding disorders
3. Taking photoactive, anti-inflammatory or anti-coagulant medication

Date of first enrolment
02/08/2022

Date of final enrolment
30/06/2023

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Salford Royal Hospital
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University/education

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ROR
https://ror.org/027m9bs27

Funder(s)

Funder type
Research council

Funder Name
Biotechnology and Biological Sciences Research Council; Grant Codes: BB/V007734/1

Alternative Name(s)
UKRI - Biotechnology And Biological Sciences Research Council, BBSRC UK, BBSRC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

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

Intention to publish date

31/12/2025

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are/will be available upon request from Prof. Cath O'Neill (catherine.o'neill@manchester.ac.uk). Reasonable requests for any study data can be made after publication, and participant consent and ethical approval have been obtained for sharing of anonymised data. The datasets generated and/or analysed during the current study will be published as a supplement to the results publication.

IPD sharing plan summary

Available on request, Published as a supplement to the results publication

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version 1.2	01/08/2022	19/10/2022	No	Yes