

# Do resident microorganisms on human skin affect the sunburn response?

<b>Submission date</b> 05/10/2022	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 19/10/2022	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 07/07/2025	<b>Condition category</b> Skin and Connective Tissue Diseases	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input checked="" type="checkbox"/> 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

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Scientific

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## Additional identifiers

### Clinical Trials Information System (CTIS)

Nil known

### Integrated Research Application System (IRAS)

317956

### Protocol serial number

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

### Study type(s)

Other

### 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(s)**

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

### **Key secondary outcome(s)**

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

### **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

### **Healthy volunteers allowed**

No

### **Age group**

Adult

### **Lower age limit**

18 years

### **Upper age limit**

40 years

### **Sex**

All

### **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**

United Kingdom

England

**Study participating centre****Salford Royal Hospital**

Stott Lane

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## Sponsor information

**Organisation**

University of Manchester

**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, Agricultural and Food Research Council, Biotechnology & Biological Sciences Research Council, BBSRC, BBSRC UK, AFRC

### Funding Body Type

Government organisation

### Funding Body Subtype

National government

### Location

United Kingdom

## 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 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?
<a href="#">Participant information sheet</a>	version 1.2	01/08/2022	19/10/2022	No	Yes