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Evaluating the sunburn protection of umbrella shade compared to sunscreen at the beach

Submission date
06/07/2016

Recruitment status
No longer recruiting

Registration date
07/07/2016

Overall study status
Completed

Last Edited
24/01/2017

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:
The use of shade, such as a beach umbrella or canopy, is one popular and convenient method for avoiding direct sun exposure when engaging in outdoor activities. However, the sun protection factor (SPF) provided by typical shade is low due to diffuse sun ultraviolet (UV) radiation in the environment. The effectiveness of the shade as a sun barrier may be influenced by a variety of factors including radius and height of the shade, the ground surface, and orientation of the measurement. The present study seeks to evaluate the real-life sun protection of typical umbrella shade compared to the real-life sun protection of a sunscreen under real-life usage conditions in a beach setting. The aim of this study is to evaluate the sunburn protection provided by a typical umbrella shade compared to an SPF 100+ sunscreen under real-life usage conditions in a beach setting.

Who can participate?
Healthy men and women over the age of 18 that are not currently sunburned, are allergic to sunscreen, or have any skin diseases.

What does the study involve?
Participants are randomly allocated to one of two groups. Those in the first group apply SPF 100+ sunscreen to the seven exposed skin areas (face, upper chest, back of the neck, both arms and legs), and are then asked to remain in the sun for at least 3 hours of 3.5 hour beach period. Participants are expected to follow directions and reapply sunscreen when needed. Those in the second group do not apply any sunscreen and are asked to remain under umbrella shade at the beach for at least 3 hours. Participants in both groups are examined around 24 hours after sun exposure so that any sunburn can be recorded. The amount of sunscreen used by participants in the sunscreen group is also measured by weighing the sunscreen bottles.

What are the possible benefits and risks of participating?
Participants benefit from receiving monetary compensation from participating in this study. There is a small risk of participants who use the sunscreen having an allergic reaction to sunscreen. There is also a risk of sunburn for all participants.

Where is the study run from?
Lake Lewisville, Texas (UK)

When is study starting and how long is it expected to run for?
August 2012 to July 2018

Who is funding the study?
Johnson & Johnson (USA)

Who is the main contact?
Dr Aaron Farberg

Contact information

Type(s)
Public

Contact name
Dr Aaron Farberg

Contact details
Mount Sinai Hospital
One Gustave L. Levy Place
New York
United States of America
10029

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
PS-1405 2911 0021-SACT

Study information

Scientific Title
A Randomized, Evaluator-Blinded, Single-Center Study Evaluating the Sunburn Protection of Typical Shade Compared to Sunscreen at the Beach

Study objectives
The aim of this study is to evaluate the sunburn protection provided by a typical beach umbrella compared to an SPF 100+ sunscreen under real-life usage conditions in a beach setting.

Ethics approval required
Old ethics approval format

Ethics approval(s)
IntegReview IRB, 01/01/2013, ref: C14-D129 (PS-1405 2911 0021-SACT)

Study design
Single-centre evaluator-blinded randomised parallel trial

Primary study design
Interventional

Secondary study design
Randomised parallel trial

Study setting(s)
Community

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

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

Interventions
At baseline, seven exposed skin areas (face, upper chest, back of the neck, both arms and legs) are examined. To qualify, participants are required to have no evidence of sunburn. Eligible participants are then randomly assigned to the Sunscreen or Shade group. A two number randomization chart is used for subjects as they are enrolled into the study.

Sunscreen group: Participants are given pre-weighed sunscreen tubes. They are monitored applying the product to all exposed areas following the label directions 15 minutes before beach exposure and are instructed to re-apply at least every 2 hours or as needed. Total sunscreen usage is recorded by weighing post-study returned tubes. Subjects are instructed to stay at the beach for 3.5 hours but may leave or stay under a shade for up to 30 minutes for cooling or rest.

Shade group: Participants are instructed to stay under the umbrella without wearing clothes that could block the evaluated areas during the study duration. They are allowed to leave the umbrella after covering up for up to 30 minutes. Positioning under the umbrella is monitored and adjusted as the solar angle changes.

Participants in both groups may not participate in water activities and time away from the beach is recorded. Sun exposure is to be avoided after the conclusion of the study until evaluation.

All participants are evaluated clinically for sunburn 22-24 hours following sun exposure by a randomization-blinded clinician. For each exposed area, a score of 0-4 is given (0 - no sunburn; 1 - possible sunburn-not clearly defined; 2 - defined redness clearly UV caused; 3 - severe sunburn-pronounced redness; 4 - edema and/or blisters). Photos are obtained for the sites >=grade 2.

Intervention Type
Other

Primary outcome measure
Clinical evaluation of sunburn is completed by a randomization-blinded clinician on a numerical rating scale approximately 24 hours after sun exposure

Secondary outcome measures
Amount/weight of sunscreen product used is recording using weighing scales at baseline and following the end of sun exposure (sunscreen group only)

Overall study start date
01/08/2012

Completion date
01/07/2018

Eligibility

Key inclusion criteria
1. Aged 18 years and over
2. Fitzpatrick Skin Type I, II, or III
3. Must be able to read and follow study instructions in English
4. Generally in good health as determined by the investigator or designee, based on collected medical history.
5. Male and female subjects with reproductive potential must agree to practice a medically acceptable form of birth control during the study and for 30 days after study completion. Females must have used such birth control for at least 3 months prior to Visit 1
6. Willing and able to follow the study instructions
7. Evidence of personally read, signed, and dated Photograph Release and Informed Consent Form (including HIPAA disclosure) indicating that the subject has been informed of and understands all pertinent aspects of the trial and is willing to participate

Participant type(s)
Healthy volunteer

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
80

Key exclusion criteria

1. Known allergies or sensitivities to topical products or ingredients in the study products
2. A history of abnormal responses to sunlight (e.g. phototoxic or photoallergic response)
3. Presence of sunburn (i.e. clinical score greater than 0), suntan, scars, tattoos, active dermal lesions, dysplastic nevi, uneven skin tone, damaged/broken skin, or excessive body hair* on the areas of skin to be evaluated
4. On the morning of or during study visits: has applied a topical product (including sunscreen, moisturizers, makeup, etc.) to the areas of skin to be evaluated (other than provided sunscreen, if applicable)
5. Taking/using systemic or topical medication that is known to alter responses to UV radiation
6. Has a concurrent illness, a medical history of a disease/condition, or a preexisting/dormant dermatologic condition (e.g., psoriasis, rashes, eczema, seborrheic, severe excoriations, etc.) that could interfere with the outcome of the study or increase health risk to the subject, as determined by the investigator or designee
7. Female subject who (to the best of her knowledge) is pregnant, lactating, or planning to become pregnant during the study or within 30 days of study completion
8. Individuals viewed by the investigator or designee as not being able to complete the study
9. Individuals who are currently participating in another clinical study or who have participated in any other clinical study in the past 4 weeks at any testing facility

Date of first enrolment
01/08/2014

Date of final enrolment
01/01/2017

Locations

Countries of recruitment
United States of America

Study participating centre
Lake Lewisville
704 W. Eldorado Parkway
Little Elm
United States of America
75068

Sponsor information

Organisation
Johnson & Johnson Consumer & Personal Products Worldwide

Sponsor details
199 Grandview Road
Skillman

United States of America
08558

Sponsor type
Industry

ROR
https://ror.org/03qd7mz70

Funder(s)

Funder type
Industry

Funder Name
Johnson and Johnson

Alternative Name(s)
Johnson & Johnson, johnson & Johnson Services, Inc., Johnson&Johnson, , Johnson & Johnson Private Limited, , J&J, JNJ

Funding Body Type
Government organisation

Funding Body Subtype
For-profit companies (industry)

Location
United States of America

Results and Publications

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

Intention to publish date
07/07/2017

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/03/2017		Yes	No