ISRCTN67760213 https://doi.org/10.1186/ISRCTN67760213

Impact of a simulated multiday heatwave on nocturnal physiology, behavior, and sleep

Submission date
17/05/2024

Recruitment status
No longer recruiting

Registration date
27/05/2024

Overall study status
Completed

Last Edited
16/07/2024

Condition category
Other

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
This study looks at how a multiday heatwave affects nighttime physiology, behavior, and sleep under controlled conditions, with careful monitoring of the environment and participant activities. The study aims to enhance our knowledge regarding the impact of heatwaves on human physiology, cognition, behavior, and sleep. Currently, there are no physiological studies investigating the impact of this unique weather phenomenon in laboratory settings that enable comprehensive and precise assessment of multiple physiological and behavioral responses in humans.

Who can participate?
Healthy young men with no history of sleep disorders or medication use

What does the study involve?
Participants will be kept in a controlled environment for ten days. The temperature will be hot-to-warm (day: 35.4°C, night: 26.3°C) during nights 4-6 and moderate (day: 25.4°C, night: 22.3°C) before (nights 1-3) and after (nights 7-10) the heatwave. Measurements to be taken include core and skin temperatures, heart rate, balance between sympathetic and parasympathetic nervous systems, indicators of skin blood flow, urine samples, blanket usage, subjective sleep quality assessments, and partial sleep monitoring.

What are the possible benefits and risks of participating?
The benefits of this study for our participants are that (i) they will learn more about the physiology of their bodies and, most importantly, (ii) they will have the opportunity to contribute to a unique state-of-the-art physiological study that will expand current knowledge on the impact of heatwaves on humans.

Regarding the risks of participating, the present study simulates a frequent weather phenomenon that participants have already experienced many times in their lives. The safety of the laboratory settings ensures that there will be no negative impacts on the health of the participants, although they may feel more tired during the heatwave simulation.

Where is the study run from?
Jožef Stefan Institute

When is the study starting and how long is it expected to run for?
June 2020 to November 2020

Who is funding the study?
1. Horizon 2020
2. Slovenian Research and Innovation Agency

Who is the main contact?
Dr Leonidas Ioannou, ioannoulg@gmail.com

Contact information

Type(s)
Public, Scientific, Principal investigator

Contact name
Dr Leonidas Ioannou

ORCID ID
https://orcid.org/0000-0001-5460-8167

Contact details
Jamova Cesta 39
Ljubljana
Slovenia
1000
+306949963364
leonidas.ioannou@ijs.si

Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
Horizon Grant No. 668786, Slovenian Research and Innovation Agency grant no. P2-0076

Study information

Scientific Title
Impact of a simulated multiday heatwave on nocturnal physiology, behavior, and sleep: A 10-day confinement study

Acronym

HEATWAVE

Study objectives
This study hypothesizes that prolonged exposure to heatwave conditions will significantly alter nocturnal physiology, thermoregulatory behavior, and sleep, including changes in the thermoregulatory mechanisms of skin vasomotion and sweating rate (reflected in urine dehydration markers), as well as variations in blanket coverage and sleep quality indicators, compared to neutral conditions.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 20/10/2020, National Committee for Medical Ethics of the Republic of Slovenia (Štefanova ulica 5, Ljubljana, 1000, Slovenia; +386 01 478 60 01; gp.mz@gov.si), ref: 0120-402 /2020/4

Study design
Interventional study

Primary study design
Interventional

Study type(s)
Quality of life, Safety

Health condition(s) or problem(s) studied
Impact of a simulated heatwave on physiology, behavior, and sleep.

Interventions
This study will monitor physiological and behavioral responses to a 3-day heatwave throughout the day and over ten days. During this period, three days (days 5 to 7) are dedicated to a heatwave (day: 35.4 °C; night: 26.3 °C) simulation, while days 1 to 4 and 8 to 10 are thermally neutral (day: 25.4 °C; night: 22.3 °C).

Intervention Type
Behavioural

Primary outcome(s)
1. Core body temperature measured using telemetric pills continuously
2. Skin temperature from four sites measured using iButtons continuously
3. Heart rate measured using heart rate monitors continuously
4. Sleep quality measured using a partial polysomnography device continuously
5. Sleep thermoregulatory behavior measured using photographs taken once per night, and with a questionnaire once per day
6. Dehydration measured using urine-specific gravity once per day

Key secondary outcome(s))
There are no secondary outcome measures

Completion date

01/11/2020

Eligibility

Key inclusion criteria
1. Non-heat acclimatized
2. Healthy, young males
3. Without a history of sleep disorders or medication use

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
Male

Total final enrolment
7

Key exclusion criteria
1. Unhealthy
2. Non-adult

Date of first enrolment
21/10/2020

Date of final enrolment
22/10/2020

Locations

Countries of recruitment
Slovenia

Study participating centre
Institut "Jožef Stefan": IJS
Jamova Cesta 39
Ljubljana
Slovenia
1000

Sponsor information

Organisation
Jožef Stefan Institute

ROR
https://ror.org/05060sz93

Funder(s)

Funder type
Government

Funder Name
Horizon 2020

Alternative Name(s)
EU Framework Programme for Research and Innovation, Horizon 2020 - Research and Innovation Framework Programme, European Union Framework Programme for Research and Innovation

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location

Funder Name
Slovenian Research and Innovation Agency

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 Dr Leonidas Ioannou, ioannoulg@gmail.com. The type of data that will be shared will be a spreadsheet file with physiological responses, which will be available five years after the data collection. Written informed consent was obtained from participants. Data are fully anonymized and stored in an encrypted format. No participant data that may affect the confidentiality (anonymity) of our participants will be shared.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		25/06/2024	16/07/2024	Yes	No
Participant information sheet		24/08/2020	22/05/2024	No	Yes
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes