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Office lighting for correction of vitamin D deficiency in winter

Submission date
22/01/2021

Recruitment status
No longer recruiting

Registration date
08/02/2021

Overall study status
Completed

Last Edited
21/06/2022

Condition category
Nutritional, Metabolic, Endocrine

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

Plain English summary of protocol

Background and study aims
Sunlight exposure to the face and forearms during summer can provide sufficient vitamin D, and people deprived of sunlight are known to be at risk of vitamin D deficiency. Adequate vitamin D is important for healthy bones and could protect against acute respiratory infections including influenza and COVID-19. The seasonal increase in respiratory infections during winter may be explained by low levels of vitamin D or possibly a direct effect of sunlight on the immune system independent of vitamin D. Also, coronavirus contamination of environmental surfaces is very sensitive to sunlight with 90% inactivated after less than 1 hour of midday sunshine during summer, while it persists for a day or more in winter. The aim of this study is to find out whether it is practical to use low-intensity ultraviolet room lighting (within EU safety regulations) during winter to prevent vitamin D deficiency in office workers, and whether it reduces respiratory infections and decreases virus contamination on exposed surfaces.

Who can participate?
Desk-based office workers at Sunderland Royal Hospital

What does the study involve?
Participants are randomly allocated to 8 weeks exposure to very low-intensity ultraviolet light equivalent to 15 minutes UK summer sunshine spread over 8 hours using the modified desk lighting, or an 8-week control period with dummy lighting. The groups then swap over for another 8-week period.

What are the possible benefits and risks of participating?
The researchers will measure participants' vitamin D levels and correct any deficiency after the study. There are no major risks of participating.

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

When is the study starting and how long is it expected to run for?
January 2020 to March 2022

Who is funding the study?
Internis Pharmaceuticals Limited (UK)

Who is the main contact?
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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)
271128

Protocol serial number
CPMS 45556, IRAS 271128

Study information

Scientific Title
Proof of concept study of low-intensity UV room lighting for correction of low levels of vitamin D in combination with dietary supplements in desk-based clerical staff during winter time

Study objectives
It is acceptable and practical to use low-intensity UV room lighting (in accordance with regulations on photo-biological safety) during winter to prevent vitamin D deficiency in office workers, and it may be suitable to use in other populations deprived of natural sunlight.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 08/07/2020, Office for Research and Ethics Committees Northern Ireland (RECB) (Business Services Organisation, Lissue Industrial Estate West, 5 Rathdown Walk, Moira Road, Lisburn, BT28 2RF, Belfast; +44 (0)2895361400; info.orecni@hscni.net), REC ref: 20/NI/0062

Study design
Open-label crossover (proposed amendment: randomized placebo-controlled crossover study)

Primary study design
Interventional

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Vitamin D deficiency

Interventions
A crossover study of 20 clerical staff using the ten prototype units, consisting of 8 weeks exposure to low-intensity UV, and 8 weeks natural UV background exposure with weekly UV dosimetry measurements and 4 weekly serum 25OHD (16 weeks in total). The proposed crossover design is AB/BA: i.e. the researchers allocate the participants into two groups; In the first period, Group 1 is under treatment A (control) and Group 2 is under treatment B (UV light); In the second period, Group 1 is under treatment B (UV light) and Group 2 is under treatment A (control). The AB/BA design is used to eliminate any period/temporal effect, though the researchers expect to see a washout effect in Group 2 in the second period (treatment A).

Daily exposure to no more than 0.7 SED narrow band UVB per eight hours +/- 15% over 37.5 hours per week to desk-based clerical and secretarial staff at Sunderland Royal Hospital using ten prototype low-intensity UV desk lights (modified “smart balance” free floor standing lighting units) for 8 weeks. The lighting unit is programmed to switch on at 08.50 am and switch off at 5.10 pm. Participants will keep a diary of time spent at their desk each day, and the clothing worn (short or long sleeves). Participants are advised not to look directly at the light fitting.

At entry: Fitzpatrick skin score, inclusion and exclusion criteria and a blood test for vitamin D. Recruitment of subjects with vitamin D less than 50. Estimation of dietary vitamin D using a

questionnaire. Allocation to crossover group. SF36 and Epworth questionnaires.
Each week throughout intervention period: changed dosimetry badge, complete UV exposure diary, telephone contact with the study coordinator.
At the completion of the intervention period: SF36, Epworth questionnaire, semi-structured interview. Each week during the control period: change dosimetry badge, telephone contact with the study coordinator.
At 4, 8, 12 and 16 weeks: blood test for vitamin D.

Intervention Type
Device

Phase
Not Applicable

Primary outcome(s)
Serum vitamin D (nmol/L) level measured using a blood sample and standard lab analysis at baseline, 4 weeks, 8 weeks, 12 weeks and 16 weeks

Key secondary outcome(s))
1. Health status measured using the SF36 questionnaire at baseline, 8 weeks and 16 weeks
2. Adverse events recorded using patients diary recording and reporting to the study coordinator during the use of the lights
3. Lethargy/sleepiness measured using Epworth sleepiness score at baseline, week 8 and week 16
4. UV exposure recorded using polysulphane badges and electronic UV trackers adjusted from time spent at desk (from patient diaries) weekly from baseline to 16 weeks

Proposed amendment:
1. Acute respiratory symptoms measured using diary throughout the study period if the participant suffers respiratory symptoms
2. Presence of influenza A and B, coronavirus, respiratory syncytial virus measured using environmental surface swabs and RT-PCR at weekly during study periods 1 and the sampling will take place towards the end of the work shift

Completion date
15/03/2022

Eligibility

Key inclusion criteria
1. Age over 18 years old
2. At least 50% of the working day (>18 hours/week) sedentary at desk base
3. Normal serum calcium, phosphate and alkaline phosphatase
4. Not currently taking oral vitamin D supplements
5. Not planning to go on any foreign holidays
6. Fitzpatrick skin types II and III
7. 25OHD less than 50 nmol/l
8. Medically fit

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Total final enrolment
19

Key exclusion criteria
1. Pregnancy
2. Patients with malignant skin conditions
3. Photosensitive medical conditions and medications (including some antibiotics) and previous photosensitive reactions
4. Unstable chronic medical conditions including inflammatory and malignant diseases
5. Planned use of sunbeds or sunny foreign trips during the study period
6. Currently taking oral vitamin D supplements
7. Individuals with severe vitamin D deficiency (hypocalcaemia, hypophosphataemia or raised alkaline phosphatase)

Date of first enrolment
01/07/2021

Date of final enrolment
15/10/2021

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Sunderland Royal Hospital
South Tyneside and Sunderland NHS Foundation Trust
Kayll Road
Sunderland
United Kingdom
SR4 7TP

Sponsor information

Organisation
South Tyneside and Sunderland NHS Foundation Trust

Funder(s)

Funder type
Industry

Funder Name
Internis Pharmaceuticals Limited

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated and/or analysed during the current study during this study will be included in the subsequent results publication
The datasets generated during and/or analysed during the current study are available from the corresponding author on reasonable request

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?
HRA research summary			28/06/2023	No	No
Other unpublished results			21/06/2022	No	No
Participant information sheet	version V6	18/01/2021	08/02/2021	No	Yes
Protocol file	version V1.3	15/01/2021	08/02/2021	No	No
Protocol file	version V1.3	16/10/2020	08/02/2021	No	No