THE STUDY PROTOCOL

date: 2024-07-16

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Title: Evaluation of the Effectiveness and Safety of Blue Light Emitted by LED Lamps Using the PHLECS Device in the Treatment of Inflammatory Skin Diseases

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• The study involves four groups of patients (patients with psoriasis, atopic dermatitis, eczema and chronic pruritus)
• The study is scheduled for a maximum of 60 irradiations of blue light (maximum 3 cycles of 20 irradiations each). Phototherapeutic light will be administered for 15 minutes to each side of the body of the patient (30 minutes in total), 3-5 times per week.
• Device
Full Body Blue GEN 1.0 device (built by PHLECS B.V., Phlecs, High Tech Campus 12, 5656 AE Eindhoven, The Netherlands) with European Community (EC) Certificate (number 2238613CE01) is used in the study. The device provides phototherapeutic light through light panel with treatment Light Emitting Diodes - LEDs (wavelength 453 nm, irradiance 40mW/cm2; dose 36J for 15min treatment) to one side of the body of the patient who is lying flat on an examination bed
• After consent to participate in this study, the observation period will begin and will last a maximum of 12 weeks

1. Day 0 - screening and inclusion, during which the following will be assessed:

- skin examination (including photo documentation), assessing skin phototype according to Fitzpatrick's scale
- detailed medical history collection
- quality of life assessment – DLQI
- Additionally, appropriate scales will be used depending on the disease:
PASI, PGA, VAS, 10-item Pruritus Severity Scale - psoriasis vulgaris
IGA, VAS, 10-item Pruritus Severity Scale - eczema
SCORAD, EASI, VAS, 10-item Pruritus Severity Scale - atopic dermatitis
VAS, 10-item Pruritus Severity Scale – chronic pruritus

- an interview will be made regarding comorbidities and the treatment used
- blood samples collection
- Optionally, only in patients who give additional consent a skin biopsy will be taken to evaluate the mechanism of action of blue light.

2. visit 1 – first full-body blue irradiation

3. Visit 2 – evaluation of the effectiveness and safety after 10 sessions of blue light phototherapy, Blood sample collection
4. Visit 3 – evaluation of the effectiveness and safety after 20 sessions of blue light phototherapy (= after the first cycle of irradiation), Blood sample collection
5. Visit 4 – evaluation of the effectiveness and safety after 30 sessions of blue light phototherapy, Blood sample collection
6. Visit 5 – evaluation of the effectiveness and safety after 40 sessions of blue light phototherapy (= after the second cycle of irradiation), Blood sample collection
7. Visit 6 – evaluation of the effectiveness and safety after 50 sessions of blue light phototherapy, Blood sample collection
8. Visit 7 - end of treatment visit - after 60 sessions of blue light phototherapy (= after the third radiation cycle), during which we will re-evaluate the condition of the skin, quality of life, safety of the device used and blood samples will be taken. Optionally, with additional consent, a skin biopsy will be taken. If, for any reason, the study is terminated earlier or if the skin lesions have completely disappeared before 60 irradiations - the end of treatment visit will take place earlier
9. Visit 8 – assessment of the clinical condition 4 weeks after the cessation of therapy

During blue light therapy, follow-up visits will be performed to assess the safety and effectiveness of the device. At the last control visit (end of treatment visit) the same parameters will be assessed as during the first one. In the case of remission of skin lesions earlier than envisaged in the study protocol, the end of treatment visit will take place earlier. Photographic documentation will be carried out at each visit. During the treatment patients were allowed to use emollients.

Inclusion criteria:
1. Informed consent to participate in a medical experiment
2. Age over 8 years of age
3. Diagnosis of psoriasis / eczema / atopic dermatitis
4. Chronic pruritus (lasting more than 6 weeks)
5. Good general health (no history of other clinically significant diseases according to the doctor's assessment)
6. A patient who is able to understand the information related to the experiment, meet the requirements contained in the protocol of the experiment, who undertakes to strictly follow medical recommendations and appear on time for visits.

Exclusion criteria:
1. Patients with known hypersensitivity to ultraviolet or blue radiation
2. Age under 8 years of age
3. Women who are pregnant, breastfeeding or planning to become pregnant during the experiment
4. Patients who participated in another experiment / clinical trial within 30 days prior to inclusion in the experiment
5. Patients unwilling or unable to respect the requirements of the experiment
6. Patients with skin diseases other than inflammatory skin diseases or chronic pruritus
7. Planned hospitalizations or surgical procedures during the medical experiment
8. Patients using medications with proven phototoxic effect
9. Diastolic blood pressure> 95mmHg and <65mmHg
10. Patients with congenital or acquired immune disorders

11. Patients with a history or at the time of the examination diagnosed with a malignant skin cancer, severe actinic keratosis or dysplastic moles
12. Patients diagnosed with genophotodermatosis, increasing the risk of skin cancers, including xeroderma pigmentosum, Cockayne's syndrome, Bloom's syndrome)
13. Patients addicted to alcohol / drugs in the last 12 months