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Feasibility study of using blue-light blocking glasses to improve quality of life for cancer patients

Submission date
11/01/2017

Recruitment status
No longer recruiting

Registration date
13/01/2017

Overall study status
Completed

Last Edited
21/02/2023

Condition category
Cancer

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

Plain English summary of protocol

Background and study aims
Many cancer patients suffer from fatigue (extreme tiredness), insomnia, depression, and other symptoms and chemotherapy side effects that make it hard to function and reduce their quality of life. These symptoms may be related to changes in circadian rhythm (the everyday rhythm of sleep and waking). Melatonin, the sleep hormone produced by our brains after dark, organizes the activity of many organs and functions of the body. The brain produces melatonin when it is dark, leading to tiredness. Studies have shown that advanced cancer patients may have lower than normal levels of melatonin. This could result in disturbed circadian rhythms: as low melatonin levels may make it harder to get to sleep and coordinate body functions this leads to complications such as fatigue and insomnia. Studies have shown that blue light can stop melatonin from being produced. Blue light given off by electric lighting and computer screens can therefore be problematic for cancer patients with already low melatonin levels. To counteract the problem of evening blue light, special glasses have been made that block blue light from entering the eyes called blue-blocker glasses. These glasses are worn from local sunset time until bed-time. The purpose of this trial is to investigate if it is possible that blue-blocker glasses increase the production of melatonin in advanced cancer patients receiving cancer treatment therefore improving their quality of life.

Who can participate?
Adults with advanced receiving treated at the Block Center for Integrative Cancer Treatment (USA)

What does the study involve?
The study takes place over the course of three chemotherapy treatments, each of which is separated by two to three weeks. Firstly, for a week before the first chemotherapy treatment patients wear actigraphs (motion-sensing devices worn on the wrist). The actigraphs assess movement and sleep, and allows researchers to precisely determine circadian rhythms of sleep, waking and activity. The evening before coming for treatment, patients collect all their urine after sunset until the first time they urinate in the morning, to measure melatonin production. Finally, they fill out questionnaires on sleep quality, depression, fatigue and quality of life.

Actigraphs, urine samples and questionnaires are brought to the clinic at the chemotherapy visit. Patients then undergo two study periods in a random order. The first involves wearing blue-blocker glasses from sunset until it is time for bed, while repeating the same activities as last week. The second involves wearing sham (dummy) glasses that do nothing to block blue light in the evenings. Participants wear the actigraphs throughout each study period to monitor their sleep rhythms. Participants also complete a number of questionnaires in order to assess their mental wellbeing before and after each treatment period.

What are the possible benefits and risks of participating?
The only potential benefit is that the glasses might increase melatonin levels and temporarily improve circadian rhythms during the week they are worn. There are a few risks of wearing blue-blocker glasses. They should be not used while outside driving or walking in the dark. Some patients might find that the glasses change colours, though household activities and reading are not impaired by the glasses.

Where is the study run from?
Block Center for Integrative Cancer Treatment (USA)

When is the study starting and how long is it expected to run for?
November 2010 to May 2014

Who is funding the study?
1. Lighting Innovations, LLC (USA)
2. Institute for Integrative Cancer Research and Education (USA)

Who is the main contact?
Dr Charlotte Gyllenhaal
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Contact information

Type(s)
Public

Contact name
Dr Charlotte Gyllenhaal

Contact details
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
2010-0372

Study information

Scientific Title
Pilot clinical trial of blue-light blocking glasses to improve cancer patient health-related quality of life

Study objectives
It is feasible to study the effects on circadian rhythms and quality of life of eyeglasses that block blue light in advanced cancer patients receiving chemotherapy. Blue-blocking glasses (blue-blockers) may increase melatonin production, which is inhibited by blue light emitted by home lighting and electronics. This may cause low melatonin levels, disrupting circadian rhythms. As cancer patients typically have abnormal circadian disruptions involving sleep problems, fatigue and other symptoms, the glasses may improve their circadian rhythms and thus their quality of life.

Ethics approval required
Old ethics approval format

Ethics approval(s)
University of Illinois at Chicago Office for the Protection of Research Subjects, 14/08/2010, ref: 2010-0372

Study design
Single-centre single-blind randomized controlled cross over trial

Primary study design
Interventional

Secondary study design
Randomised cross over trial

Study setting(s)
Hospital

Study type(s)
Quality of life

Participant information sheet
No participant information sheet available

Health condition(s) or problem(s) studied
Advanced or metastatic cancer

Interventions
The study takes place over three study visits, separated by two to three weeks. All patients begin with a baseline observational period, and then participate in both blue-blocking eyeglasses and sham eyeglasses treatment periods. Randomization is determined by even or

odd random numbers. All study periods occur in the 7 days before a planned treatment visit at the study clinic.

Baseline period: no study glasses are worn.

Blue-blocking eyeglasses: participants wear amber-colored plastic glasses that block blue light over 530 nm in wavelength from entering the eyes. Eyeglasses are worn beginning at local sunset time and taken off at bedtime (night-lights that do not emit blue light are supplied for safety during nocturnal activity).

Sham eyeglasses: participants wear placebo glasses which are yellow-colored plastic glasses that transmit all wavelengths equally. Eyeglasses are worn beginning at local sunset time and taken off at bedtime (night-lights that do not emit blue light are supplied for safety during nocturnal activity).

In each study period, patients wear wrist actigraphs (Motion-Logger, Ambulatory Monitoring, Inc, Ardsley, New York, USA) continuously to measure rest and activity. They also keep daily sleep logs. On the last night before the clinic visit, patients collect all urine after sundown through the time of the first morning urination, and bring it to the clinic. On the last day of the treatment period, patients fill out the study questionnaires: Pittsburgh Sleep Quality Index, Hospital Anxiety and Depression Scale, EORTC Quality of life, Powers and Ferrans Quality of life, and Piper Fatigue Scale.

Intervention Type
Device

Primary outcome measure
1. Circadian organization of sleep and activity rhythms as measured by actigraphy. The 24-hour autocorrelation of motion levels at each time of day for all intervention days will be the main actigraphic variable is measured using the actigraphy during the baseline, blue-blocker and sham glasses study periods.
2. Level of urinary 6-sulfatoxymelatonin in overnight urine sample at the end of the baseline, blue-blocker and sham glasses study periods

Secondary outcome measures
1. Self-assessed nocturnal sleep using the Pittsburgh Sleep Quality Index (PSQI) and a sleep log at the end of the baseline, blue-blocker and sham glasses study periods
2. Cancer-associated self-assessed anxiety and depression using the Hospital Anxiety and Depression Scale at the end of the baseline, blue-blocker and sham glasses study periods
3. Self-assessed daytime fatigue as measured by Pittsburgh Sleep Quality Index at the end of the baseline, blue-blocker and sham glasses study periods
4. Self-assessed cancer-related quality of life using the EORTC and Powers and Ferrans Quality of Life scales at the end of the baseline, blue-blocker and sham glasses study periods
5. Self-assessed fatigue using the Piper Fatigue Scale at the end of the baseline, blue-blocker and sham glasses study periods

Overall study start date
24/08/2010

Completion date
31/05/2014

Eligibility

Key inclusion criteria
1. Histologically confirmed, advanced or metastatic cancer (solid tumors other than brain, esophageal or pancreatic cancer)
2. Patients with more than one malignancy or with a prior malignancy are eligible to participate, if that other cancer is currently under control
3. Life expectancy of 6 months or more in the judgment of the treating physician
4. Patient must be scheduled to receive at least 3 cycles of chemotherapy, other systemic anti-cancer therapy, or ongoing active palliative care
5. Patient may start this study at any cycle in their treatment, and any reasonable cycle length is acceptable as long as measurements can be taken before each treatment
6. Any number of previous treatments with chemotherapy and/or other systemic targeted therapies are permitted
7. Prior or concurrent treatment on another clinical trial is not exclusionary for participation
8. ECOG Performance Status of 0, 1, or 2

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
30

Key exclusion criteria
1. Active concomitant malignancy not currently under control
2. Women who are pregnant, breast-feeding or planning to become pregnant during the study
3. Less than 30 days from major surgery
4. Less than 30 days from radiation therapy
5. Uncontrolled/Symptomatic brain or CNS metastases
6. Symptomatic spinal cord compression
7. Uncontrolled psychiatric disorders that would prevent participation in the study in the judgment of the treating physician
8. Serious co-morbidity that would interfere with the patient’s capacity to participate in the study in the judgment of the treating physician
9. Blindness from any cause
10. Night shift workers
11. Melatonin supplementation

Date of first enrolment
01/11/2010

Date of final enrolment
31/05/2014

Locations

Countries of recruitment
United States of America

Study participating centre
Block Center for Integrative Cancer Treatment
5230 Old Orchard Road
Skokie
United States of America
60077

Sponsor information

Organisation
Block Center for Integrative Cancer Treatment

Sponsor details
5230 Old Orchard Road
Skokie, Illinois
United States of America
60077

Sponsor type
Hospital/treatment centre

Website
http://www.blockmd.com

ROR
https://ror.org/03vk8p158

Funder(s)

Funder type
Not defined

Funder Name
Lighting Innovations, LLC

Funder Name
Institute for Integrative Cancer Research and Education

Results and Publications

Publication and dissemination plan
1. Report of study results, 2017
2. Review article on integrative therapies and circadian rhythms in cancer

Intention to publish date
31/12/2017

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

IPD sharing plan summary
Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		23/05/2022	21/02/2023	Yes	No