A study on the influence of dynamic light on sleep an circadian rhythm, in long-stay patients on a haematology ward.

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON21353

Source
NTR

Brief title
Dynamic light study

Health condition

Intensive chemotherapy, intensieve chemotherapie, AML, ALL, Burkitt lymphoma, Burkitt lymfoom, mantle cell lymphoma, mantelcellymfoom, multiple myeloma, multipel myeloom

Sponsors and support

Primary sponsor: Erasmus Medical Center
TNO
Source(s) of monetary or material Support: Erasmus Medical Center
TNO

Intervention

Outcome measures

Primary outcome

Difference in wakefullness during the time presumed sleeping between both groups.

Secondary outcome

1. Subjective quality of sleep;

2. Depression;

3. Delirium as diagnosed by a psychiatrist;

4. Clinical parameters (complications, blood pressure, heart rate, temperature, pain score);

5. Duration of hospitalization;

6. Medication with special attention to benzodiazepines, antipsychotics, antidepressants, corticosteroids, and other medication with known psychiatric side effect (such as voriconazole).

Study description

Background summary

N/A

Study objective

Artificial dynamic lightening can positively influence the sleep/wake cycle and reduce the disturbance of the circadian rhythm due to hospitalization.

Study design

Enrolment (demographic data, medical diagnosis, medication, sleep pattern by Munich Chronotype Questionaire, global clinical impression by staff).

During study:

1. Continuous:

Actigraphy by actiwatch, environmental parameters ie vertical and horizontal illuminance levels (due to daylight and/or artificial light), use of sunscreens and/or curtains, use and adjustment by patients/staff of all lighting systems in the room, room temperature, room humidity, position patient (bed or chair), outdoor vertical and horizontal illuminance levels;

2. Once daily:

Heart rate, blood pressure, temperature, quality of sleep (Groninger Sleep Quality Scale);

3. Two times per week:

Pain scored by numeric rating scale (NRS);

4. Weekly:

Hospital anxiety depression scale (HADS), delirium (as weekly revised by a psychiatrist), complications (as noted in the decursus), use of benzodiazepines, antipsychotics, antidepressants, corticosteroids, other medication, WHO performance score, frequency and duration of swith off the study light due to medical reasons or on patients request;

5. Once during admission:

Evaluation of lighting system itself by patients;

6. Periodical:

Noise, ventilation, air flow;

7. At the end of the study:

Global clinical impression by staff, length of stay;

8. In case of early cessation of patient participation:

Reason of cessation;

9. At the end of the entire study period:

Evaluation of lighting system by staff.

Intervention

On the haematology ward of the hospital, 9 single-bed rooms will be equipped with dynamic light as well as standard light. The design of the study is a randomized controlled trial. Patients will be randomized to dynamic light or standard light for their entire stay. If during a subsequent stay (ie second episode) patients participate again, they will be switched to the opposite condition.

Contacts

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Eligibility criteria

Inclusion criteria

1. Patient at least 18 yrs old;

2. Admitted to the haematology dept in a private patient room equipped with dynamic light as well as standard light;

3. Written informed consent;

4. Expected length of stay approx 3 weeks with room arrest;

5. Patients requiring intensive chemotherapy, due to AML, ALL, Burkitt lymphoma, mantle cell lymphoma, and multiple myeloma.

Exclusion criteria

1. Active depression;

2. Visual handicapped due to ocular pathologies like macula degeneration, severe cataract or severe diabetic retinopathy;

3. Sleep apnoe syndrome;

4. Extreme light sensitivity;

5. Insufficient fluency in Dutch language.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	17-01-2012
Enrollment:	80
Type:	Anticipated

Ethics review

Positive opinion

Date:	28-12-2011
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL3069
NTR-old	NTR3217
Other	METC Erasmusmc : 2011-174

Study results

Summary results
N/A