PAMAL

Pedometer Activity Monitoring After ASCT

NCT-Nummer:
NCT03238599

Studienbeginn:
November 2017

Letztes Update:
14.01.2020

Wirkstoff:
-

Indikation (Clinical Trials):
Lymphoma

Geschlecht:
Alle

Altersgruppe:
Erwachsene (18+)

Phase:
Phase 2

Sponsor:
University Hospital Inselspital, Berne

Collaborator:
-

Studien-Informationen

Detailed Description:

Patient-reported outcome measures (PROMs) Cancer patients experience significant physical and psychosocial consequences of cancer and treatment which affect quality of life (QoL). These consequences may be under-recognized and under-treated in oncology practice, resulting in greater morbidity that is costly to patients and the health system. Patient-reported outcome measures (PROMs) are advocated for use in routine cancer clinical practice for early detection of distress and as a performance metric for evaluating the quality of care on health outcomes.

A PROM is defined as 'any report coming directly from the patient about a health condition and its treatment using a self-reported measure. PROMs focus on physical symptoms, treatment toxicities, psychosocial problems or global health-related quality of life (HRQoL) impacts of a health condition. PROMs that capture the whole-person impact of cancer and treatments on health outcomes are increasingly recommended by patients, clinicians, and decision makers.

A number of implementation issues related to the use of PROMs data need to be considered: (i) limiting data collection so as to minimize patient burden and completion time, (ii) collecting PROM data at baseline and selected follow-up times while minimizing the number of assessments, (iii) considering whether measurement equivalence has been established when using different modes of patient-reported data collection (e.g. web, telephone, tablet, or paper), (iv) collecting data via electronic technologies whenever possible, and (v) employing methods to minimize missing data including educating site personnel, patients and clinicians, and real-time monitoring of adherence.

Step counting devices to monitor physical activity The intensive medical treatment of patients with hematologic malignancies is associated with numerous long-term adverse effects, including anemia, fatigue, and reduced physical exercise capacity. Patients with hematologic malignancies may benefit from physical exercise programs in terms of maintenance or even improvement in fatigue, physical activity, and fitness levels. Since many patients with hematologic malignancies are young and professionally active, regaining physical activity is a prerequisite for timely resuming professional activities, and, thus, of immediate socio-economic relevance. A major component of daily physical activity and the most common form of exercise is walking. Walking is self-regulated in intensity, duration, and frequency, and it can be an important indicator of a person's health and fitness status. The improvement of functional status is a primary goal in the rehabilitation of cancer patients. It is thus crucial to be able to document quantitatively the walking activity of patients who are recovering from intensive medical treatment. An understanding of the quantity (or lack) of walking activity seems particularly important in addressing the needs of cancer patients who are recovering from intensive medical treatment

Patients with hematologic malignancies recovering from intensive medical treatment such as after high-dose chemotherapy (HDCT) and autologous stem cell transplantation (ASCT) can benefit from gradually regaining a more physically active lifestyle, typically by increasing ambulatory activity. Step counting devices (accelerometers and pedometers) offer an opportunity to monitor daily ambulatory activity. Tudor-Locke and Bassett originally proposed a graduated step index to describe pedometer-determined habitual physical activity in adults:

1. < 5,000 steps/day (sedentary);

2. 5,000-7,499 steps/day (low active);

3. 7,500-9,999 steps/day (somewhat active);

4. ≥ 10,000-12,499 steps/day (active); and

5. ≥12,500 steps/day (highly active).

Recognizing a considerable floor effect (i.e., insensitivity to the range of activity levels below the lowest threshold) when applied to low active populations, Tudor-Locke et al suggested that the

original sedentary level is further divided into two additional incremental levels:

< 2,500 steps/day (basal activity) and 2,500- 4,999 steps/day (limited activity).

Prospective use of PROMs and step counting devices after ASCT The investigators here propose a non-randomized prospective non-blinded non-interventional observational clinical phase II study, assessing physical activity in myeloma and lymphoma patients following high-dose chemotherapy (HDCT) with autologous stem cell transplantation (ASCT). The primary objective is to determine whether regaining a daily activity of at least 5'000 steps (thus, regaining the "low active" level) 30 days after HDCT with ASCT is associated with a higher probability to resume professional activity.

The hypothesis will be that 50% or more of those patients who achieve >5'000 steps during one day at least once between 10 and 30 days after ASCT will have resumed their professional activities at the day 100 assessment, whereas only 30% of those patients, who have not achieved the 5'000 steps threshold until day 30, will have restarted their professional life at the day 100 assessment. Physical activity will be assessed by a web-based pedometer device, and patient-reported outcome measures (PROMs) will be collected using a web-based tool.

The MIDATA.coop platform The trial will use the MIDATA.coop platform based on the principle of citizen-controlled data storage and sharing. MIDATA.coop embodies an IT platform managing personal data and the governance needed to operate it. As a not-for-profit citizen-owned cooperative, its vision is to allow citizens to collect, store, visualize, and share specific sets of their personal data with friends and health professionals, and to make anonymized versions of part of these data accessible to research projects in fields that appeal to them. The value generated by this secondary use of personal data is managed collectively to operate and extend the platform and support further research projects.

Ein-/Ausschlusskriterien

Inclusion Criteria:

- Patients with plasma cell disorders (myeloma and amyloidosis) or with lymphomas (NHL and Hodgkin) undergoing high-dose chemotherapy with autologous stem cell transplantation.

- Patients must be aged 18-65 years.

- Patients must have given voluntary written informed consent.

- Patients without professional activity (such as due to early retirement, dependency on disability reimbursement, or unemployment) are eligible.

Exclusion Criteria:

- Patients with other serious medical condition that could potentially interfere with the completion of treatment according to this protocol.

- Lack of patient cooperation to allow study treatment as outlined in this protocol.

Studien-Rationale

Primary outcome:

1. Professional Activity (Time Frame - 100 days):
Number of patients who resumed their professional activity within 100 days after ASCT.

Secondary outcome:

1. Physical activity (Time Frame - 100 days):
Web-based patient reported physical activity assessed by digital step counting after autologous transplant.

2. Febrile Episodes (Time Frame - 100 days):
Web-based patient reported febrile episodes after autologous transplant.

3. Well-being (Time Frame - 100 days):
Web-based patient reported well-being assessed by digital follow-up reporting after autologous transplant.

Geprüfte Regime

- Pedometer-based activity monitoring after ASCT:
  Measurement of physical daily activity using a digital step counter (Pedometer-based activity monitoring) and assessment of patient well-being using a web-based patient reported tool.

Studienleiter

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Status: Rekrutierend

Quelle: ClinicalTrials.gov