Treatment of Targeted Therapy-Related Fatigue in Patients with CML or GIST: A Single-Case Experimental Design

Published: 29-12-2014
Last updated: 21-04-2024

To investigate the efficacy of cognitive behaviour therapy (CBT) on reducing TTF in patients receiving TKIs for CML or GIST.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Miscellaneous and site unspecified neoplasms malignant and unspecified
Study type	Interventional

Summary

ID

NL-OMON41733

Source
ToetsingOnline

Brief title
Single-Case Experiment in Patients with TTF

Condition

- Miscellaneous and site unspecified neoplasms malignant and unspecified

Synonym
Chronic Myeoloid Leukemia, Gastro-intestinal stromal tumour

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Sint Radboud
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Chronic myeoloid leukemia, Fatigue, Gastro-intestinal stromal tumour, Targeted therapy

Outcome measures

Primary outcome

Fatigue severity is the primary outcome measure of the proposed SCE.

Secondary outcome

Not applicable

Study description

Background summary

Targeted therapies are a new generation of cancer drugs designed to interfere with molecular targets critical for tumor growth and progression. One of the first and most successful examples of targeted therapy is imatinib, a tyrosine kinase inhibitor (TKI) developed for chronic myeloid leukemia (CML) but now also applied in patients with a metastatic gastro-intestinal stromal tumour (GIST). Although TKIs are much better tolerated than regimens they replaced, they still posses side effects that are bothersome to patients, interfere with quality of life (QoL), and contribute to problems with adherence. Since treatment typically continues on a daily basis for many years and may be life-long, effective management of side effects is critically important. Recent studies show that fatigue is the most common symptom identified by patients being treated with TKIs. The proposed study represents the first attempt to address the problem of targeted therapy-related fatigue (TTF).

Study objective

To investigate the efficacy of cognitive behaviour therapy (CBT) on reducing TTF in patients receiving TKIs for CML or GIST.

Study design

The research methodology used in the proposed research is a single-case experiment (SCE). SCEs are experimental, and its purpose is to document causal relationships between independent and dependent variables.

Intervention

Participants will receive CBT for fatigue in addition to usual care. CBT will consist of approximately 14 individual one-hour sessions over a period of 26 weeks. The CBT will be given by trained therapists at the Expert Center for Chronic Fatigue of the Radboud university medical center (Radboudumc). This treatment is already part of routine care for severely fatigued patients who have completed curative cancer treatment at least three months previously.

Study burden and risks

There are no or only minimal risks involved in participating in the CBT intervention. The burden is limited and consists of extra travelling for the sessions, following max. 14 sessions of CBT, and doing home-work assignments. The program is adapted to the individual situation of the patient. Patients fill out several questionnaires at baseline measurement, in order to determine which topics need to be included in the CBT. During the complete study period (min. 37 to max. 56 weeks) patients will complete a short weekly questionnaire. This questionnaire can be completed online, via an iPod, or as a paper-and-pencil version, within approximately 5-10 minutes. There are substantial potential benefits for participants, as CBT for fatigued disease-free cancer survivors already proved to be a highly effective intervention in reducing fatigue and disabilities and it is likely that patients with TTF will also profit and become less fatigued and disabled.

Contacts

Public
Universitair Medisch Centrum Sint Radboud

Reinier Postlaan 4
Nijmegen 6525GC
NL
Scientific
Universitair Medisch Centrum Sint Radboud

Reinier Postlaan 4
Nijmegen 6525GC
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

• Age of 18 years or above;
• Able to speak, read, and write Dutch;
• Diagnosed with CML or GIST;
• Receiving (chronic) treatment with a tyrosine kinase inhibitor (TKI) for at least 3 months;
• Being severely fatigued (CIS fatigue >= 35), without known and treatable somatic causes for fatigue.

Exclusion criteria

• Receiving treatment for a psychiatric disorder

Study design

Design

Study phase:	3
Study type:	Interventional
Intervention model:	Other
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	26-03-2015
Enrollment:	10
Type:	Actual

Ethics review

Approved WMO Date:	29-12-2014
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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
CCMO	NL51370.091.14