Long-Term Functional Results of Ewing Tumor Treatment

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Ethical review	Approved WMO
Status	Recruiting
Health condition type	Musculoskeletal and connective tissue neoplasms
Study type	Observational non invasive

Summary

ID

NL-OMON36450

Source
ToetsingOnline

Brief title
Long-Term Functional Results of Ewing Tumor Treatment

Condition

- Musculoskeletal and connective tissue neoplasms

Synonym
Ewing tumor, skeletal malignancy

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Ewing tumour, Late effects, Locomotion

Outcome measures

Primary outcome

The results will be used to identify those changes in functional capacity that likely result in long-term physical, intellectual, or psychological problems, and to develop strategies for reducing long-term effects of different therapeutic approaches.

Secondary outcome

The secondary objective is to establish and upgrade a unique data pool of 2700 Ewing patients that allows to perform differential analyses of diagnostic, treatment, and follow-up data from childhood cancer patients covering a period of 30 years. Prognostic factors for long-term survival will be obtained. Risk ratios for survival between treatment options will be computed to combine long-term functional and survival outcome results. Guidelines for future treatment practice and long-term follow-up will be provided.

Study description

Background summary

Ewing tumors are the second most common bone tumors in childhood and adolescence. The short-term clinical outcome is well known with about 70% surviving, however, valid information on the long-term functional outcome is very limited. To minimize the clinical, economic and social late effects of treatment it is necessary to examine long-term survivors with objective and self-report instruments.

Study objective

The primary objective is to measure the real-world daily activity in a representative cohort of 1100 longterm survivors after Ewing tumor treatment using portable devices, and to describe the functional outcome and health-related quality of life associated with different chemotherapeutic regimens and local surgical and radiotherapeutic techniques. All scores will be compared to a peer control group of equal size matched according to age, sex and other potential bias factors.

Study design

Included patients will be asked to fill in a questionaire based on the Toronto Extermity Salvage Score, the MOS Short Form Healty Survey SF36 (patients> 18 years) and the PEDQL (for patients < 18 years) of age and the Rosenberg self esteem score, the EORTC modules about body image and sexuals qualitiy functioning. Functional activity will be measured by wearing a Cyma Step Activity Monitor around the ankle for 14 days during daytime. Survival analyses will be done on all patients to build the basis for evaluating functional outcome in relation to survival probabilities and their co-variation relative to different therapy approaches. For every long-term survivor one peer of the patient will be recruited to control for potential bias factors

Study burden and risks

Burden will be
1. Filling in a single questionnaire
2. wearing a strap around the ankle for 14 days (except during nighttimes and during bathing routines.

Risks
1. circulation problem in case the strap is fitted to tight.

Benefits;
1. Prognostic factors for long-term survival will be obtained.
2.Risk ratios for survival between treatment options will be computed to combine long-term functional and
survival outcome results.
3.Guidelines for future treatment practice and long-term follow-up will be provided.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

This is a cohort study that will include all patients with histologically confirmed Ewing tumor of the
previous CESS 81, CESS 86, EICESS 92 and ongoing EURO-E.W.I.N.G. 99 (expected closing date end of 2008) of the German Society for Pediatric Oncology and Hematology (GPOH). Additionally, all Ewing tumor patients will be included who have been registered as follow-up patients to the Ewing tumor trail center in Münster from 150 participating institutions in Germany and about 30 additional centers in the neighboring countries. (Among them the AMC)

Exclusion criteria

Patients with any kind of paralysis will be excluded from the functional measurement (<1%) as the daily activity could not objectively be measured with step monitors.

Study design

Design

Study phase:	4
Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Prevention

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-08-2011
Enrollment:	65
Type:	Actual

Ethics review

Approved WMO

Application type:	First submission
Review commission:	METC Amsterdam UMC

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	NL34483.018.10