The validation of a clinical screening instrument for tumor predisposition syndromes in childhood cancer patients

Gepubliceerd: 22-12-2015 Laatst bijgewerkt: 18-08-2022

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Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON25524

Bron
Nationaal Trial Register

Verkorte titel
TuPS

Aandoening

Childhood Cancer Patients

Ondersteuning

Primaire sponsor: The Academic Medical Center, Amsterdam, The Netherlands
Overige ondersteuning: KiKa, Stichting Kinderen Kankervrij

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Sensitivity of the screening instrument

Toelichting onderzoek

Achtergrond van het onderzoek

The inclusions for the TuPS studie will start in the first few months of 2016 in the six academic pediatric oncology clinics in the Netherlands and their allied clinical genetic departments: Emma Children's Hospital/Academic Medical Center Amsterdam, Maastricht University Medical Center, VU medical centre Amsterdam, Sophia Children's Hospital/Erasmus Medical Center, Wilhelmina Children's Hospital/University Medical Center Utrecht, Beatrix Children's Hospital/University Medical Center Groningen, University Medical Center Nijmegen.

Doel van het onderzoek

It is estimated that 7 percent of patients who develop cancer as a child have a tumor predisposition syndrome (TPS)(Merks et al, Am J Med Genet A, 2005). It is of significant clinical relevance to recognize a TPS as it may lead to recognition of other, non-tumor signs and symptoms, may affect treatment regimes, allows suitable cancer surveillance strategies, offers insights in the prognosis of the child, and can facilitate adequate genetic counselling of the child and his or her family members. Recent research in the Netherlands has shown that half of the tumor predisposition syndromes were not recognized by the physicians involved in the care of a child with cancer (Merks et al., Am J Med Genet A, 2005). The best way to detect a TPS is by evaluation by a clinical geneticist. However, referring all paediatric cancer patients for clinical genetic evaluation is impossible in current clinical practice due to capacity problems and has financial consequences.

We argue that an easy-to-use and easy to implement screening instrument that can be used in all childhood cancer patients and detect patients at risk for having a TPS could serve as a standard screen for genetic counselling. This would guarantee that for each childhood cancer patient the presence of a TPS is considered. Such screening instrument should be easily completed by a genetic nurse, genetic counsellor or treating physician. The screening tool should be based on the manifestations of known TPS, as these manifestations have been shown to indicate the cancer susceptibility. Part of manifestations in TPS will be visible on two-dimensional (2D) and three-dimensional (3D) pictures. We have recently identified the most important and sensitive manifestations of known TPS using a two-round Delphi process with eight international content-experts (Hopman et al., Eur J Cancer, 2013).

We developed such a screening instrument. The screening instrument consists of a question form, clinical photographic pictures and a 3D picture of the face of the patient.
The primary goal of the TuPS study is to validate this clinical screenings instrument for TPS in childhood cancer patients.

Onderzoeksopzet

Sensitivity: after complete consult clinical geneticist (routine genetic consultation)

Specificity: after complete consult clinical geneticist (routine genetic consultation)

Onderzoeksproduct en/of interventie

All the included patients will be invited for a consult with a genetic counselor. During this consult, the score form will be filled in and the medical photographer will make 2D and 3D pictures of the patient.

All this data will be uploaded to a secured online database. Two independent clinical geneticist form another center then the patient will be asked to assess this screening package. Patients in whom a genetic condition is suspected by one or more clinical geneticists will follow routine genetic consultation. In addition, we will ask 20% of the patient in whom no genetic condition is suspected by both clinical geneticists to also follow routine genetic consultation. This selection will be random, using the online randomization database ALEA. Both the clinical geneticist as the patients and their parents who are seen for a routine genetic consultation will not know the result of the assessment of the screening package.

Contactpersonen

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- the age of 0 to 18 years

- a newly diagnosed malignancy

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- diagnosed with a syndrome, which is associated with the current malignancy

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Anders

Controle: N.v.t. / onbekend

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-01-2016
Aantal proefpersonen:	1000
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	22-12-2015
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL5461
NTR-old	NTR5605
Ander register	KiKa : 143

Resultaten