Nephroblastoma Clinical Trial and Study.

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To continue a risk-adapted stratification of therapeutic intensity, incorporating response to pre-operative chemotherapy, in all children with Wilms tumour and other renal tumours of childhood. To test the treatment hypothesis that doxorubicin is...

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON23585

Bron
NTR

Verkorte titel
SIOP 2001

Aandoening

Local stage II or III intermediate risk nephroblastoma after pre-operative chemotherapy and surgery.

Ondersteuning

Primaire sponsor: Emma Kinderziekenhuis AMC, Amsterdam (the Netherlands).
UKCCSG Data Centre, University of Leicester (UK); Universitätsklinik für Kinder- und Jugendsmedizin (Germany).
Séverine Guillemaut, Unité de Biostatistiques et d'Evaluation des Thérapeutiques (France).
Overige ondersteuning: Stichting Kindergeneeskundig Kankeronderzoek (the Netherlands).
Deutsche Krebshilfe (Germany).
Barncancerfonden (Sweden).

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Event Free Survival (EFS).

Toelichting onderzoek

Achtergrond van het onderzoek

N/A

Doel van het onderzoek

To continue a risk-adapted stratification of therapeutic intensity, incorporating response to pre-operative chemotherapy, in all children with Wilms tumour and other renal tumours of childhood.

To test the treatment hypothesis that doxorubicin is not necessary in patients with intermediate risk tumours and local stage II or III by a multicentre prospective randomised trial.

To determine prospectively the prognostic significance of specific histological subtypes following pre-operative chemotherapy, as specified in the protocol. In particular, the study aims to: confirm the adverse prognostic significance of the blastemal predominant subtypes and whether this can be offset by intensifying therapy and investigate the hypothesis that the epithelial and stromal-predominant subtypes have a favourable prognosis and investigate the prognostic significance of the percentage necrosis after pre-operative chemotherapy in relation to the type and amount of residual viable tumour.

To minimise acute and late toxicity without jeopardising event free and overall survival by reducing treatment for: patients with focal anaplasia, and patients with stage I, intermediate risk tumours.

To determine prospectively the prognostic significance of tumour volume following pre-operative chemotherapy and its relation to histological subtype.

To determine prospectively the prognostic significance of specimen weight at time of nephrectomy and its relation to histological subtype.

To reduce the number of drug administrations, hospital visits and thereby costs in the preoperative phase.

Onderzoeksproduct en/of interventie

Establishing equivalence between 2 post-operative treatments. Trialarm with Doxorubicine versus Trialarm without Doxorubicin.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. All localised disease nephroblastoma patients age more than 6 months or less than 18 years at time of diagnosis.

Unilateral tumour with clinical and ultrasonic characteristics compatible with nephroblastoma or biopsy proven histological diagnosis.

2. Written informed consent and national ethical committee approval.

3. Stage II and III intermediate risk histology after pre-treatment according to protocol and after operation.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. All other kind of renal tumours of infancy.

2. Patients without previous anti-tumour treatment.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Blindering:	Dubbelblind
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-06-2002
Aantal proefpersonen:	350
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	12-03-2005
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	NL33
NTR-old	NTR58
Ander register	: N/A
ISRCTN	ISRCTN16583459

Resultaten

Samenvatting resultaten
N/A