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Nephroblastoma clinical trial and study

Submission date 04/08/2005	**Recruitment status** No longer recruiting	[ ] Prospectively registered [ ] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [ ] Record updated in last year
Registration date 04/08/2005	**Overall study status** Completed	
Last Edited 29/10/2021	**Condition category** Cancer	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
NTR58

Study information

Scientific Title

Nephroblastoma clinical trial and study

Acronym
SIOP 2001

Study objectives
1. 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
2. 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
3. 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.
4. 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
5. To determine prospectively the prognostic significance of tumour volume following pre-operative chemotherapy and its relation to histological subtype
6. To determine prospectively the prognostic significance of specimen weight at time of nephrectomy and its relation to histological subtype
7. To reduce the number of drug administrations, hospital visits and thereby costs in the preoperative phase

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval received from local ethics committee.

Study design
Randomised, double-blind, active controlled, parallel group trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Nephroblastoma

Interventions
Establishing equivalence between two post-operative treatments. Trial arm with doxorubicin versus trial arm without doxorubicin.

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Doxorubicin

Primary outcome measure
Event free survival (EFS).

Secondary outcome measures
No secondary outcome measures

Overall study start date
01/06/2002

Completion date
01/06/2009

Eligibility

Key inclusion criteria
1. All localised disease nephroblastoma patients age more than 6 months or less than 18 years at time of diagnosis
2. Unilateral tumour with clinical and ultrasonic characteristics compatible with nephroblastoma or biopsy proven histological diagnosis
3. Written informed consent and national ethical committee approval
4. Stage II and III intermediate risk histology after pre-treatment according to protocol and after operation

Participant type(s)
Patient

Age group
Child

Lower age limit
6 Months

Upper age limit
18 Years

Sex
Both

Target number of participants
350

Total final enrolment
583

Key exclusion criteria
1. All other kind of renal tumours of infancy
2. Patients without previous anti-tumour treatment

Date of first enrolment
01/06/2002

Date of final enrolment
01/06/2009

Locations

Countries of recruitment
Netherlands

Study participating centre
SIOP Nephroblastoma Trial and Study Office
Amsterdam
Netherlands
1105 AZ

Sponsor information

Organisation
Academic Medical Centre (AMC) (The Netherlands)

Sponsor details
Emma Kinderziekenhuis
Postbus 22660
Amsterdam
Netherlands
1105 AZ

Sponsor type
University/education

Website
http://www.amc.uva.nl/

ROR
https://ror.org/03t4gr691

Funder(s)

Funder type
Research organisation

Funder Name
The Foundation of Paediatric Cancer Research (Stichting Kindergeneeskundig Kankeronderzoek [SKK]) (The Netherlands)

Funder Name
German Cancer Aid (Deutsche Krebshilfe) (Germany)

Funder Name
The Swedish Childhood Cancer Foundation (Barncancerfonden) (Sweden)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan
Not provided at time of registration

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Plain English results		21/07/2015	29/10/2021	No	Yes