

Nephroblastoma clinical trial and study

Submission date 04/08/2005	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 04/08/2005	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 29/10/2021	Condition category Cancer	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

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