Fasting Intervention for children with Unilateral Renal Tumours to reduce Toxicity

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON27995

Source
NTR

Brief title
The FIURTT-Study

Health condition

Acute kidney injury, renal tumours

Sponsors and support

Primary sponsor: Princess Máxima Center for Paediatric Oncology (Investigator-Initiated)
Source(s) of monetary or material Support: Princess Máxima Center for Paediatric Oncology (Investigator-Initiated)

Intervention

Outcome measures

Primary outcome

The incidence of Acute Kidney Injury (AKI) on postoperative day 3 (48-72 hours after end of anaesthesia)

Secondary outcome

Postoperative renal function, postoperative renal injury, side effects, adherence to fasting, change in fasting parameters, body weight, subject wellbeing, physical activity, neuromotor performance, duration of postoperative hospital stay, admission to ICU, expression of cytoprotective/anti-oxidant genes.

Study description

Background summary

Rationale:
Childhood renal tumours account for around 7% of all childhood cancers. Most of these cases are Wilms tumour, around 90%. The annual incidence of renal tumours is seven cases per million children younger than 15 years. In the Netherlands, the SIOP-RTSG approach is considered standard of clinical care, it consists of preoperative chemotherapy and surgical excision. Postoperative chemo- and radiation therapy is advised on a risk-based approach. For Wilms tumours, the use of these regimens has resulted in excellent survival rates, the overall five-year survival rates are approaching 90 percent. Efforts to decrease toxicity are now being pursued.

Caloric restriction (CR), meaning reduced intake of food without malnutrition, is associated with extended life span, lower risk of age associated diseases, increased resistance against side-effects of chemotherapy, improved fitness and increased resistance to acute stress. Nutritional preconditioning, by long-term CR or short-term fasting, represents a non-invasive, non-expensive method of mitigating the effects of acute surgery-induced stress. It increases expression of cytoprotective genes, immunomodulation via increased anti-inflammatory cytokine production and decreases the expression of pro-inflammatory markers. As surgery is an important part of renal tumour treatment, preoperative fasting could be introduced to further improve outcomes. Since renal tumour patients undergo a well-defined therapeutic regimen in which chemotherapy and surgery do not overlap, this leaves a well-defined preoperative time window required to perform preoperative fasting.

Objective: to investigate the effect of a preoperative fasting diet on postoperative renal function recovery after renal tumour surgery.

Study design: a single-centre, prospective, randomized, non-blinded, intervention study

Study population: children between 6 months and 18 years of age, diagnosed with a unilateral renal tumour, opting for curative treatment including preoperative chemotherapy and subsequent surgical excision of the renal tumour.

Intervention: nutritional preconditioning by preoperative fasting for 10, 14 or 18 hours.

Main study parameters/endpoints: the incidence of Acute Kidney Injury (AKI) on postoperative

day 3.

Study objective

We aim to investigate the effect of a preoperative fasting diet on postoperative renal function recovery after renal tumour surgery.

Study design

2 and 1 weeks before surgery, 1 day before surgery, and 1-5 days after surgery, 2 and 4 weeks after surgery

Intervention

Preoperative fasting for 10, 14 or 18 hours, intervention duration depends on subject age

Contacts

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Eligibility criteria

Inclusion criteria

Patients diagnosed with and/or a strong clinical suspicion of a unilateral malignant renal tumour without metastatic disease (either WT, RT, CCS, RCC, CMN, etc.) at Princess Máxima Centre for Paediatric Oncology. Since biopsy and therefore histological diagnosis of the type of renal tumour is not mandatory preoperatively, there needs to be a strong clinical suspicion or diagnosis of a renal tumour, opting for surgical excision after preoperative chemotherapy (treatment planned according to SIOP-RTSG-UMBRELLA).

Inclusion criteria: unilateral localized renal tumours, not metachronous, planned radical

tumour-nephrectomy, adequate understanding of the Dutch language.

Exclusion criteria

Bilateral renal involvement, anorexia / very low body weight (for subjects younger than 1 year: SD-score < -2 for weight by age, for subjects older than 1 year: SD-score < -2 for weight by height), underlying metabolic disease prohibiting a period of fasting, metastatic disease, unilateral local and metachronous disease, no curative treatment possible or opting for Nephron-Sparing Surgery (NSS).

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	22-04-2021
Enrollment:	50
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	22-04-2021
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 54486
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL9422
CCMO	NL75103.041.21
OMON	NL-OMON54486

Study results