

Fasting Intervention for children with Unilateral Renal Tumours to reduce Toxicity

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

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

Samenvatting

ID

NL-OMON27995

Bron

Nationaal Trial Register

Verkorte titel

The FIURTT-Study

Aandoening

Acute kidney injury, renal tumours

Ondersteuning

Primaire sponsor: Princess Máxima Center for Paediatric Oncology (Investigator-Initiated)

Overige ondersteuning: Princess Máxima Center for Paediatric Oncology (Investigator-Initiated)

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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

Onderzoeksopzet

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

Onderzoeksproduct en/of interventie

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

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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).

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blinding:	Open / niet geblindeerd
Controle:	Actieve controle groep

Deelname

Nederland	
Status:	Werving gestart
(Verwachte) startdatum:	22-04-2021
Aantal proefpersonen:	50
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum: 22-04-2021
Soort: Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 54486
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten