Fasting Intervention for children with Unilateral Renal Tumours to reduce Toxicity

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to investigate the effect of a pre-operative fasting diet on post-operative recovery after renal tumour surgery

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Renal and urinary tract neoplasms malignant and unspecified
Study type	Interventional

Summary

ID

NL-OMON54486

Source
ToetsingOnline

Brief title
The FIURTT-Study

Condition

- Renal and urinary tract neoplasms malignant and unspecified
- Renal disorders (excl nephropathies)
- Renal and urinary tract therapeutic procedures

Synonym
Malignant Renal Tumor, Nephroblastoma, Renal tumor

Research involving
Human

Sponsors and support

Primary sponsor: Prinses Máxima Centrum voor Kinderoncologie
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Fasting, Pediatric Oncology, Renal Tumor, Surgery

Outcome measures

Primary outcome

Primary endpoint: The incidence of Acute Kidney Injury (AKI) on post-operative day 3 (48-72 hours after end of anaesthesia)

Secondary outcome

Secondary endpoints: post-operative renal function, post-operative renal injury, side effects, adherence to fasting, change in fasting parameters/molecular markers, body weight, subject wellbeing, physical activity, anuria/oliguria, duration of post-operative hospital stay, admission to ICU, expression of cytoprotective/anti-oxidant genes

Study description

Background summary

Childhood renal tumours account for around 7% of all childhood cancers. The majority of these cases (90%) are Wilms tumour (WT or Nephroblastoma). The annual incidence of renal tumours is seven cases per million children younger than 15 years. Most patients with a renal tumour are asymptomatic, or they present with a painless abdominal mass or haematuria. In the Netherlands, the SIOP-RTSG approach is considered standard of clinical care. The current SIOP-RTSG-2016 UMBRELLA protocol (further referred to as *UMBRELLA*) consist of pre-operative chemotherapy and surgical excision. Post-operative chemotherapy and radiation therapy is advised by a risk based approach. For Wilms tumors, the use of recent international SIOP-RTSG regimens has resulted in excellent survival rates and efforts to decrease in toxicity are now being pursued. The overall five-year survival rates approaching 90 percent.

Dietary restriction (DR), meaning reduced intake of food without malnutrition, and intermittent fasting are 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 DR or fasting) represents non-invasive, non-expensive methods of mitigating the effects of acute surgery-induced stress. Short-term DR and fasting increases expression of cytoprotective genes, increases immunomodulation via increased anti-inflammatory cytokine production and also decreases the expression of pro-inflammatory markers. Nutritional preconditioning has been proven feasible and safe in well-nourished patients before surgery.

As surgery is an important part of renal tumour treatment, nutritional preconditioning could be introduced to further improve patients* therapy outcomes. Since renal tumour patients undergo a well-defined therapeutic regimen in which chemotherapy and surgery do not overlap, this leaves a well-defined pre-operative time window required to perform pre-operative fasting.

Study objective

to investigate the effect of a pre-operative fasting diet on post-operative recovery after renal tumour surgery

Study design

a single-centre, prospective, randomized, non-blinded, proof-of-concept intervention study

Intervention

Nutritional preconditioning by fasting for 10, 14 or 18 hours.

Age Group 1: 6-24 Months (0,5 to 2 years): 10 hours of fasting
Age Group 2: 25-84 Months (2 to 7 years): 14 hours of fasting
Age Group 3: 85-216 Months (7 to 18 years): 18 hours of fasting

Study burden and risks

The extent of the burden of our study is considered relatively low. DR and fasting has been proven feasible and safe in previous studies. For this study, no extra blood samples are taken besides the samples taken for routine procedures. No extra visit to the hospital is needed in order to obtain all the information required for this study. Biopsies acquired to investigate the tissue are part of the routine procedure. Several standardized questionnaires are asked to be filled in before and after the diet. Mentioned questionnaires take +/-10 minutes to complete. The diet may give rise to discomfort in the form of less satiety and possible light-headedness.

Based on earlier research we propose different fasting duration per paediatric age group. We hypothesize that subjects of a younger age need significantly less time to reach the protective state associated with fasting and we aim to avoid unnecessary exposure to the risk of developing prolonged or severe hypoglycemia.

Combining the low chance of post-operative complications, the small extent of possible post-operative complications and our clear guidelines to avoid hypoglycaemia, we do not expect a higher incidence of complications or any compromises on subject safety. Conducting this research will bring invaluable knowledge concerning a minimal invasive therapy with no extra cost and its possible merits for pre-operative conditioning to reduce the post-operative burden.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)

Children (2-11 years)
Babies and toddlers (28 days-23 months)

Inclusion criteria

Children and young adolescents within the age range of 6 months up and until 19 years are eligible for this study. In order to further be eligible to participate in this study, a subject must meet all of the following criteria:
- Written consent of parent(s)/caregiver(s)/legal representative
- Subject written consent when older than 12 years
- Unilateral localized renal tumours, not metachronous
- Planned radical tumour-nephrectomy
- Adequate understanding and/or mastery of the Dutch language

Since biopsy and therefore histological diagnosis of the type of renal tumour is not acquired pre-operatively, there needs to be a strong clinical suspicion or diagnosis of a renal tumour, opting for surgical excision after pre-operative chemotherapy (treatment planned according to SIOP-RTSG-UMBRELLA).

Exclusion criteria

A potential subject who meets any of the following criteria will be excluded from participation in this study:
- Bilateral renal involvement
- Anorexia / very low body weight
o Subjects younger than 1 year: SD-score < -2 for weight by age
o Subject older than 1 year: SD-score < -2 for weight by height
- Underlying metabolic disease prohibiting a period of fasting
- Metastatic disease
- Unilateral local, metachronous disease
- Diabetes Mellitus Type 1 or 2
- No curative treatment possible
- Opting for Nephron-Sparing Surgery (NSS)

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial

Masking:	Open (masking not used)

Primary purpose: Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	30-08-2021
Enrollment:	50
Type:	Actual

Ethics review

Approved WMO

Date:	15-04-2021
Application type:	First submission
Review commission:	METC NedMec

Approved WMO

Date:	03-08-2023
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

ID: 27995
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL75103.041.21

Register	ID
OMON	NL-OMON27995