The Association Between Sleep Duration and Sleep Disorders and Proteinuria in Children

CLINICALTRIALS.GOV IDENTIFIER	RECRUITMENT STATUS	FIRST POSTED	LAST UPDATE POSTED
NCT03933046	NOT YET RECRUITING	MAY 1, 2019	MAY 1, 2019

STUDY DESCRIPTION

Brief Summary

The presence of protein in urine is a common laboratory finding in children. Although proteinuria is usually benign, it can be a marker of a serious underlying renal disease or systemic disorder. Microalbuminuria can be one of the first subclinical manifestations of endothelial dysfunction and is associated with low grade systemic inflammation. Multiple studies from the adult population suggest that microalbuminuria above the upper quartile is linked with increased risk of coronary heart disease and death even after adjustment for the presence of diabetes mellitus, obesity and hypertension. Obstructive sleep apnea (OSA) has been recognized as an independent risk factor for cardiovascular morbidity related to sympathetic nervous system overflow, metabolic dysregulation, inflammation and endothelial dysfunction secondary to repetitive hypoxia -reoxygenation events. Therefore, there is a need for further studies to investigate the association between OSA and microalbuminuria in children. Furthermore, no studies have thus far investigated the association between other sleep disorders such as periodic limb movement (PLMD) and microalbuminuria in children. Our hypothesis is that children with sleep disorders or short sleep duration have increased risk of proteinuria/microalbuminuria and that treatment and resolution of the sleep problem will be followed by improvement in proteinuria levels.

Condition or Disease: OSA
Proteinuria
Periodic Limb Movement Sleep Disorder

Intervention/treatment: Diagnostic Test: PSG

Phase: N/A

DETAILED DESCRIPTION

200 children aged 2-18 years that will be referred to the Sleep Disorders Center for overnight polysomnography due to suspected sleep disordered breathing or PLMD will be recruited to the study during their first visit in the sleep clinic. During that study, an informed consent will be completed by the parents. Data on weekdays and weekends sleep duration as well as personal and family history of kidney disease will be collected.
Exclusion criteria:1. Known renal disease; 2. diabetes mellitus; 3. current use of ACE inhibitors or angiotensin receptor blockers; 4. neuromuscular disorders or craniofacial abnormalities; 5. syndromic conditions.
All participants will undergo physical examination. Weight and height will be measured, and body mass index (BMI) z-score will be calculated.
Blood pressure will be measured on the first visit in the sleep clinic by a trained physician as specified in recent guidelines. 19
Overnight polysomnography will be carried out in the Sleep Disorders Laboratory and the following signals will be recorded: electroencephalogram (EEG; C3/M2, C2/M1, O1/M2, O2/M1); right and left oculogram; submental and tibial electromyogram; body position; electrocardiogram; thoracic and abdominal wall motion; oronasal airflow (three-pronged thermistor and nasal pressure transducer); and oxygen saturation of hemoglobin (SpO2). Arousals, sleep stages and respiratory events will be scored, and polysomnography indices will be defined according to the recent American Academy of Sleep Medicine recommendations . 20
First void urine samples will be collected in a sterile cup the morning following the polysomnography (6:00-7:00 am). For each sample urinalysis, protein/creatinine and albumin/creatinine will be measured. Urinary albumin and protein excretion will be the primary outcome measure. Proteinuria will be defined as protein/creatinine greater than 0.2 and albuminuria will be defined as albumin/creatinine above age-adjusted limits Children who will be diagnosed with moderate-severe OSA will be referred to an ENT surgeon for adenotonsillectomy, the first line of treatment in pediatric OSA. Six to 10 weeks following surgery, these children will be requested to undergo additional PSG evaluation. First void urine samples will be collected the following morning.
In addition- 100 children referred to the pediatric nephrology clinic due to asymptomatic albuminuria/proteinuria will be recruited. Parents will be required to complete a designated sleep questionnaire that includes items on sleep duration, SDB and RLS symptoms. Exclusion criteria, as described above for the entire cohort, will also apply to this subpopulation.
Informed consent will be completed by the parents.

STUDY DESIGN

Study Type:	Interventional
Estimated Enrollment :	300 participants
Intervention Model :	Single Group Assignment
Masking:	None (Open Label) ()
Primary Purpose:	Screening
Official Title:	The Association Between Sleep Duration and Sleep Disorders and Proteinuria in Children
Estimated Study Start Date:	May 2019
Estimated Primary Completion Date:	May 2021
Estimated Study Completion Date:	September 2021

ARMS AND INTERVENTIONS

Arm	Intervention/treatment
Experimental: children referred to PSG due to suspected SDB	Diagnostic Test: PSG polysomnography and urine analaysis for protein levels

OUTCOME MEASURES

Primary Outcome Measures: 1. morning urine protein/creatinine >0.2 [Time Frame: 1 year]
2. reported sleep duration (hours) [Time Frame: 1 year]
3. morning urine protein/creatinine >0.2 post treatment of OSA [Time Frame: 1 year]

ELIGIBILITY CRITERIA

Ages Eligible for Study: 2 to 17 Years (Child)

Sexes Eligible for Study: All

Accepts Healthy Volunteers: Yes

Criteria

Inclusion Criteria:
1. age: 2-17 years
2. Referred to overnight PSG due to suspected OSA or PLMD
3. referred for evaluation in the nephrology clinic due to proteinuria

Exclusion Criteria:
1. Known renal disease;
2. diabetes mellitus;
3. current use of ACE inhibitors or angiotensin receptor blockers;
4. neuromuscular disorders
5. craniofacial abnormalities
6. syndromic conditions.

CONTACTS AND LOCATIONS

Contacts

Locations

Sponsors and Collaborators

Tel-Aviv Sourasky Medical Center

Investigator

MORE INFORMATION

Responsible Party :	Tel-Aviv Sourasky Medical Center
ClinicalTrials.gov Identifier :	NCT03933046
Other Study ID Numbers :	0134-19-TLV
First Posted :	May 1, 2019
Last Update Posted :	May 1, 2019
Last Verified :	April 2019
Studies a U.S. FDA-regulated Drug Product:	No
Studies a U.S. FDA-regulated Device Product:	No
Keywords provided by Tel-Aviv Sourasky Medical Center:	*periodic limb movement disorder* *children osa* *proteinuria*
Additional relevant MeSH terms :	*Disease* *Sleep Wake Disorders* *Parasomnias* *Proteinuria*