

# Sodium accumulation in the skin of children.

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<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruiting
<b>Health condition type</b>	Other condition
<b>Study type</b>	Observational non invasive

## Summary

### ID

NL-OMON49448

### Source

ToetsingOnline

### Brief title

Salt-Kids study

### Condition

- Other condition

### Synonym

Non-osmotic sodium accumulation, Salt regulation

### Health condition

Fysiologie van natriumbalans

### Research involving

Human

## Sponsors and support

**Primary sponsor:** Academisch Medisch Centrum

**Source(s) of monetary or material Support:** Ministerie van OC&W

## Intervention

**Keyword:** Cardiovascular risk factors, Glycosaminoglycans, Skin, Sodium accumulation

## Outcome measures

### Primary outcome

Primary endpoint will be the sodium content of the skin, expressed in mmol per g dry weight in correlation with cardiovascular risk factors.

### Secondary outcome

Skin GAG composition, residing macrophages, capillary, and lymphatic density (i.e., skin changes that relate to a high sodium-induced BP rise) and BP represent secondary outcome measures.

## Study description

### Background summary

Rationale: The role of high sodium intake in blood pressure (BP) and worse cardiovascular health has been extensively investigated, but is to date still incompletely understood. For a long time, it was thought that sodium homeostasis in the body was based on a two-compartment model, which assumed that an increase in dietary salt intake leads to a water shift from the intracellular to the extracellular compartment, thirst and increased renal water uptake. These effects, to maintain plasma osmolality, and thus increase in extracellular volume was considered to be mainly responsible for BP increases. However, consecutive long-term sodium balance studies have shown no weight gain or increase in total body water during a high sodium intake. It was found that sodium can accumulate non-osmotically in tissue interstitium and the

endothelial surface layer (ESL), thus forming a third sodium compartment in the body. Highly sulfated glycosaminoglycans (GAGs) are thought to facilitate tissue sodium accumulation, but also increased immune cell infiltration into tissues. How these phenomena affect BP is unknown. Yet, modification in GAG status by oral GAG supplementation has recently been shown to lower BP. Large variations in skin sodium accumulation capacity have been found in various pathological conditions associated with worse cardiovascular health, including high BP. Whether this third compartment is relevant in early life and whether alterations of tissue sodium accumulation at a young age may translate in BP alterations and worse cardiovascular (CV) outcome later in life is unknown.

## **Study objective**

Objective: The aim of this study is to define: i. the environmental and biological factors that drive skin sodium accumulation according to the novel 3-compartment concept in the skin of children; ii. whether these factors are associated with risk factors for future cardiovascular disease; and iii. the association between skin sodium accumulation and alterations in GAG metabolism and local immune cell infiltration.

## **Study design**

This study has a multicenter observational study design.

## **Study burden and risks**

The findings of this study will contribute to our understanding of the ability of the skin to accumulate sodium non-osmotically in healthy, children without the need to perform a skin or tissue biopsy for the purpose of this study. Furthermore, it will give more insight in the association between non-osmotic sodium accumulation and already known risk factors for worse CV health. Participation in this research will not lead to personal benefit for the subjects. There will be no burden to the study subjects, except of children at age of 5 or higher in whom BP will be measured. Furthermore, subjects\* parents will be requested to participate in two questionnaires and BP levels will be measured in all parents.

## **Contacts**

### **Public**

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## **Trial sites**

### **Listed location countries**

Netherlands

## **Eligibility criteria**

### **Age**

Children (2-11 years)

### **Inclusion criteria**

Healthy, male children undergoing a circumcision  
Parents / caregivers capable of giving written informed consent and able to comply with the requirements listed in the informed consent form.

### **Exclusion criteria**

Unwillingness from the parents to let their child participate in the study  
Parents who are not capable of giving written informed consent and able to comply with the requirements listed in the informed consent form  
Contraindication for circumcision  
One or both parents who are not capable of reading and understanding the Dutch patient information letter

## **Study design**

## Design

**Study type:** Observational non invasive

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Basic science

## Recruitment

NL

Recruitment status: Recruiting

Start date (anticipated): 27-02-2021

Enrollment: 500

Type: Actual

## Ethics review

Approved WMO

Date: 22-09-2020

Application type: First submission

Review commission: METC Amsterdam UMC

Approved WMO

Date: 24-12-2020

Application type: Amendment

Review commission: METC Amsterdam UMC

Approved WMO

Date: 09-04-2021

Application type: Amendment

Review commission: METC Amsterdam UMC

## Study registrations

### Followed up by the following (possibly more current) registration

No registrations found.

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

No registrations found.

## In other registers

Register	ID
CCMO	NL72920.018.20