Non-osmotic sodium storage in placental tissue in hypertensive and normotensive pregnancies

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON27314

Source
NTR

Brief title
NOSIP

Health condition

- Pregnancy induced hypertension
- Chronic hypertension in pregnancy
- Early-onset pre-eclampsia
- Late-onset pre-eclampsia

Sponsors and support

Primary sponsor: Amsterdam UMC – location AMC
Source(s) of monetary or material Support: - Amsterdam UMC – location AMC, Department of Vascular Medicine
- Personal grant PI

Intervention

Outcome measures

Primary outcome

Differences in the amount of non-osmotic sodium storage in placental tissue between hypertensive pregnancies (including chronic hypertension, gestational hypertension, late-onset and early-onset pre-eclampsia) and normotensive pregnancies.

Secondary outcome

- Differences in the distribution of non-osmotic sodium storage in placental tissue;
- Differences in the expression of GAGs in placental tissue between hypertensive and normotensive pregnancies.

Study description

Background summary

The existing idea about sodium handling in the body postulates that total body sodium is regulated by strict regulation of body fluid. However, recent studies suggest non-osmotic sodium (Na+) storage in the skin. Active Na+ storage independent of volume retention is thought to be facilitated by negatively charged, highly sulfated GAGs which are able to bind Na+ in an osmotically inactive manner and are abundantly expressed in the insterstitium of the skin. Research has shown that high sodium diet increases the non-osmotic Na+ content of the skin and is correlated with the synthesis of new glycosaminoglycans. Furthermore, research has shown that sodium storage in the skin possibly influences blood pressure regulation by mechanisms which involve the immune system. GAGS are also highly expressed in the placenta and are known to have anticoagulant, inflammatory and pro-antigenic properties. Moreover, in previous studies it was found that during PE the amount of GAGs expressed in placental tissue differed when compared to normotensive controls. We previously conducted a pilot experiment in which we found that the placenta may also act as a buffer for non-osmotic sodium storage. Besides we found that in late-onset pre-eclampsia the placenta possibly loses this function. However, this pilot experiment was subjected to several limitations. Therefore, in this prospective cohort study we aim to further investigate a possible role for the placenta as non-osmotic sodium buffer during pregnancy and differences in this ability between normotensive pregnancies and pregnancies complicated by a hypertensive disorder.

This study is designed as a multi-center study (OLVG + Amsterdam UMC – location AMC). After screening for eligibility and given informed consent, additional information will be collected by a questionnaire (printed version or EPIC). Prior to delivery blood plasma will be collected for additional measurements of plasma sodium, osmolality and GAG analysis. Additional information about the pregnancy, the delivery and the newborn will be extracted from the electronic patient file. After delivery the placenta is send to the pathology

department of the hospital, where the placental tissue will be analyzed.

Study objective

Like the skin, the placenta is a buffer for non-osmotic sodium storage and acts as an adaptive mechanism to deal with increased sodium. We postulate that pregnancies with a hypertensive disorder will differ in their amount of non-osmotic sodium storage when compared to normotensive pregnancies.

Study design

- Third trimester of pregnancy
- Postpartum

Contacts

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Eligibility criteria

Inclusion criteria

- Aged 18 years or above;
- Uncomplicated pregnancy or hypertensive disorder of pregnancy defined as: pregnancy induced hypertension, chronic hypertension in pregnancy, early-onset pre-eclampsia or late-onset pre-eclampsia;
- Gestational age between 28 weeks to 40 0/7 weeks.

Exclusion criteria

- Pregnant women aged <18 years;

- Pregnant women with multiple pregnancies;
- Diagnosis of end stage renal disease;
- Medical history of diabetic disease;
- Presence of a known congenital anomaly;
- Presence of congenital infections;
- Unwillingness to participate in the study or to cede the placenta after delivery.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	18-03-2019
Enrollment:	150
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	03-04-2019
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 48312
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL7640
CCMO	NL68080.018.18
OMON	NL-OMON48312

Study results