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

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Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON27314

Bron
Nationaal Trial Register

Verkorte titel
NOSIP

Aandoening

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

Ondersteuning

Primaire sponsor: Amsterdam UMC – location AMC
Overige ondersteuning: - Amsterdam UMC – location AMC, Department of Vascular Medicine
- Personal grant PI

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

- Third trimester of pregnancy
- Postpartum

Contactpersonen

Publiek

Amsterdam UMC - location AMC
Marjet Oppelaar

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Wetenschappelijk

Amsterdam UMC - location AMC
Marjet Oppelaar

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- 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.

Belangrijkste redenen om niet deel te kunnen nemen

(Exclusiecriteria)

- 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.

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Parallel
Toewijzing:	Niet-gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	18-03-2019
Aantal proefpersonen:	150
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:	03-04-2019
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 48312
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten