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

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The main goal is to investigate if non-osmotic sodium storage in placental tissue, analogous with the skin, is harmful and associated with hypertensive disorders in pregnancy.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Placental, amniotic and cavity disorders (excl haemorrhages)
Study type	Observational non invasive

Summary

ID

NL-OMON48312

Source
ToetsingOnline

Brief title
Non-osmotic sodium storage in placental tissue

Condition

- Placental, amniotic and cavity disorders (excl haemorrhages)

Synonym
high blood pressure in pregnancy, Hypertensive disorder of pregnancy

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Glycosaminoglycans, Hypertensive disorder of pregnancy, Non-osmotic sodium storage

Outcome measures

Primary outcome

The chief parameter we will be studying is the difference in the amount of

non-osmotic sodium storage in placental tissue, defined as sodium content per

dry weight, between placentas of hypertensive pregnancies and normotensive

pregnancies.

Secondary outcome

• The distribution of non-osmotic sodium storage in placental tissue;

• The difference in GAG expression.

Study description

Background summary

Non-osmotic sodium storage by glycosaminoglycans (GAGs) in the skin interstitium and the endothelial surface layer (ESL) is a novel concept. It reveals that the existing idea about sodium homeostasis in the body is more difficult then we have considered it to be for years. Negatively charged, highly sulfated glycosaminoglycans are able to bind sodium in an osmotically inactive manner. These GAGs are abundantly expressed in the skin insterstitium and the endothelial surface layer (ESL) and are covalent attached to proteoglycans. Research have shown that high sodium diet both increases ESL stiffness as the sodium content of the skin. In humans, high sodium skin content is associated with a variety of pathological conditions, such as hypertension and chronic kidney disease. GAGs are also highly expressed in the placenta and have known anticoagulant, inflammatory and pro-antigenic properties. Despite an increased understanding of the roles of placental GAGs in the extracellular matrix, it is unknown if these GAGs contribute to non-osmotic sodium storage and if non-osmotic sodium storage differs between normotensive pregnancies and pregnancies complicated by a hypertensive

disorder.

Study objective

The main goal is to investigate if non-osmotic sodium storage in placental tissue, analogous with the skin, is harmful and associated with hypertensive disorders in pregnancy.

Study design

This study is designed as a multi-center(OLVG + AMC) case-control study. After screening for eligibility patients are informed about the study and ask for informed consent. After given informed consent all subjects will fill in a questionnaire to collect information regarding demographic characteristics, medical history, co-morbidity, medication usage and obstetric history. Medical information about the current pregnancy, the delivery and the new born will be extracted from the electronic patient file. Prior to delivery two extra vials of blood will be collected for additional measurements of plasma sodium, osmolality and GAG analysis. The placenta is send to the pathology department of the hospital. Biopsies are taken for specific regions of the placenta. Water content, electrolyte concentrations and GAGs expression are measured in all biopsies.

Study burden and risks

The results of this study are beneficial to our understanding of the placenta as non-osmotic buffer for sodium storage and the role of non-osmotic sodium storage in hypertensive disorders of pregnancy. The burden and risks of participation are negligible, considering the placenta as a waste product after child-birth. There is no individual benefit from participation in this study.
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Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- Pregnant women aged >= 18 years with a hypertensive disorder of pregnancy (pre-eclampsia, HELLP syndrome, gestational hypertension, chronic hypertension in pregnancy)
- Gestational age between 28 weeks to 40 0/7 weeks;
- Healthy subjects should be aged >= 18 years, normotensive during the whole pregnancy and matched for gestational age.

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:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	28-06-2019
Enrollment:	150
Type:	Actual

Ethics review

Approved WMO Date:	22-03-2019
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	04-06-2019
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	16-07-2019
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	24-07-2020
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

ID: 27314
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL68080.018.18
OMON	NL-OMON27314