Periodontal status in early-onset preeclamptic women versus late preeclamptic women and normals, directly postpartum

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To determine and compare the periodontal status between the different groups of women. Periodontal examinations will be performed within one week after delivery. If periodontal disease is diagnosed within the selected groups, it is plausible to...

Ethical review	Approved WMO
Status	Pending
Health condition type	Bacterial infectious disorders
Study type	Observational invasive

Summary

ID

NL-OMON30971

Source
ToetsingOnline

Brief title
Early onset versus late onset preeclampsia and periodontitis

Condition

- Bacterial infectious disorders
- Maternal complications of pregnancy

Synonym
preeclampsia

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Periodontitis, Preeclampsia, Subgingival bacteria

Outcome measures

Primary outcome

Presence and severity of periodontal disease.

Secondary outcome

Microbial composition of the sugingival plaque.

Genetic profile.

Markers of inflammation in bloodserum.

Study description

Background summary

Recent studies suggest a significant association between maternal periodontal disease and preeclampsia. The etiology of preeclampsia however is still not clear. A recent thought is that mild infection of the bloodvessels during normal pregnancy results in activation of the endothelium, mild activation of the coagulation cascade and a mild reduction in fibrinolysis. It has been hypothesized that preeclampsia is an exaggerated immune response in the bloodvessels with more pronounced endothelial damage and an induced activation of the coagulation cascade. Several riskfactors play a role in the pathogenesis of this syndrome. The presence of a chronic infection during pregnancy is thought to be an important riskfactor for preeclampsia. Periodontal disease is a chronic infection of the supporting tissues of the teeth, which can be present subclinically for years. We hypothesise that the presence of periodontal disease during pregnancy might play a role in the pathogenesis of preeclampsia.

Two forms of preeclampsia can be distinguished: early-onset preeclampsia (occurring <34 weeks of pregnancy) and late-onset preeclampsia (occurring >34

weeks of pregnancy). Although placental dysfunction plays a central role in the development of both forms of this syndrome, boths forms differ in pathogenesis. Early-onset preeclampsia is associated with low birth weight en starts with (genetically predisposed) abnormal placentation, leading to reduced placental perfusion and a hypoxic placenta. This abnormal placentation and fetal growth restriction is not seen in late-onset preeclampsia. Late-onset preeclampsia seems to be an abnormal maternal response. Late-onset preeclampsia is thought to be the result of a maternal haemodynamic failure to comply with the additional demands of the feto-placental unit. The endothelial damage that causes the clinical syndrome of preeclampsia resembles the endothelial abnormalities as seen in atherosclerosis. Especially women with a history of early-onset preeclampsia seem to be at higher risk for cardiovascular diseases in later life. A history of early-onset preeclampsia might thus be a predictor for the development of cardiovascular diseases in later life.

Study objective

To determine and compare the periodontal status between the different groups of women. Periodontal examinations will be performed within one week after delivery. If periodontal disease is diagnosed within the selected groups, it is plausible to assume periodontal disease was present during pregnancy.

Study design

Clinical case-control study, in which the periodontal condition, genetic profile and microbiological composition of the subgingival plaque of the different groups will be determined.
One extra blood sample, drawn from the antecubital vein of patients during routine vein puncture, will be taken at the moment of hospitalization.

Study burden and risks

The periodontal screening, microbial test and genetic screening will take about 1 hour. The used periodontal screenings will not be painful, but can sometimes be experienced as inconvenient.
One extra blood sample, drawn from the antecubital vein of patients during routine vein puncture, will be taken.

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

Caucasian origin
Primigravida
Cesarean delivery
Within the early-onset preeclamptic group: dysmaturity

Exclusion criteria

Smoking during pregnancy
Pre-existing hypertension
Diabetes mellitus
Renal disease
Cardio-vascular disease
Systemic illness
Periodontal treatment
Absence of >8 teeth (incl. third molars)
Antibiotic medication during pregnancy
Multiple pregnancy
Within the late-onset preeclamptic and normal groups: dysmaturity

Study design

Design

Study type:	Observational invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-01-2008
Enrollment:	105
Type:	Anticipated

Ethics review

Approved WMO

Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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	NL18149.042.07