Quantification of PEth to determine alcohol consumption by pregnant women, a prospective prevalence study

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Primary Objective: -To explore the percentage of positive total PEth levels in blood, as a proxy of alcohol consumption, in pregnant women during their first visit to the obstetrics department.Secondary Objectives: To explore the distribution of...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Other condition
Study type	Observational invasive

Summary

ID

NL-OMON43553

Source
ToetsingOnline

Brief title
IMPACT

Condition

- Other condition

Synonym
Alcohol consumption

Health condition

Ontwikkeling van het (ongeboren) kind

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Alcohol consumption, Phosphatidylethanol, Pregnancy

Outcome measures

Primary outcome

Total PEth-concentration in blood; this is based on the sum of POPEth, PLPEth

en DOPEth concentration (ng/ml).

Secondary outcome

POPEth-concentration (ng/ml)

PLPEth-concentration (ng/ml)

DOPEth-concentration (ng/ml)

Age

Ethnicity

Gravidity

Parity

Reported alcohol consumption

Gestational age

Haemoglobin concentration

Postal code (numbers only)

Study description

Background summary

Alcohol consumption during pregnancy is known to cause damage to the unborn child. It influences both the physical and neurobehavioral development of the fetus. The (visible) effects and developmental problems of these children are referred to as fetal alcohol spectrum disorder (FASD) or fetal alcohol syndrome (FAS). FASD is characterized by a broad spectrum of symptoms, which are not necessarily present at the same time or in the same extent. FAS is the most serious variant of these disorders. Children with FAS meet the following criteria: growth deficiency, three FAS facial dysmorphic signs, central nervous system abnormalities (including cognitive and behavioural developmental disorders and microcephaly), and maternal alcohol exposure . In North America, FASD currently represent the leading cause of mental retardation, ahead of Down syndrome and cerebral palsy . Although recent data are unknown for the Netherlands, it is estimated that in the Netherlands every year at least 135 children are born with FAS and 400 with FASD. Today, health care providers assume that these numbers are much higher because FAS and FASD are often misdiagnosed.

To what extent low to moderate alcohol consumption does cause FASD or FAS still remains unclear. However, there is a clear relation between excessive alcohol consumption and FAS in children these women gave birth to. A study among pregnant British women suggest that both pregnant women and women planning to conceive, should be advised to abstain from alcohol. They state that even women consuming 1-2 drinks up to two times a week are at risk of having babies with reduced birth weight and born preterm, compared to women who abstained from alcohol . They also found the effect of alcohol to the fetus to be the strongest during the first trimester. On the contrary, a Dutch study found that low-to-moderate alcohol consumption by pregnant women did not adversely affect fetal growth characteristics. Although these studies show different results, it is important to realise that they only focus on fetal growth and birth weight and it is often difficult to diagnose FAS or FASD in those early stages of life.

Another point to take into account is the fact that these studies on alcohol consumption during pregnancy are based on questionnaires. When self-reporting on alcohol consumption is compared with meconium testing for fatty acid ethyl esters, a degradation product of alcohol, the meconium test was positive 4-13 times as often as would be expected on the self-reports. The inconsistency in study results might be caused by unreliable data of self-reports. Therefore, a reliable biomarker to detect alcohol consumption is highly desirable.

Phophatidylethanol (PEth) is a direct alcohol marker which is formed in the cell membranes of red blood cells by means of phospholipase D. PEth is a very specific metabolite, since it is formed exclusively in the presence of ethanol and can therefore not be detected in non-drinkers. Furthermore, PEth remains detectable in blood for an average period of at least two weeks. This offers potential for retrospective detection of alcohol over a longer period. Such analyses are desirable for pregnant women since they underreport to

questionnaires. When their alcohol consumption from even several weeks ago can be objectified, these women can be offered special counselling programs. This might prevent further alcohol consumption, will protect the fetus and therefore reduce the number of children born with FAS and FASD. And even more important, PEth can help us find possible relationships between alcohol consumption during pregnancy and characteristics of the women that consume while pregnant. And therewith we might be able to enter better education on women whom meet these characteristics before they become pregnant.

Study objective

Primary Objective:
-To explore the percentage of positive total PEth levels in blood, as a proxy of alcohol consumption, in pregnant women during their first visit to the obstetrics department.

Secondary Objectives:
To explore the distribution of POPEth, PLPEth and DOPEth levels in blood, as a proxy of alcohol consumption, in pregnant women during their first visit to the obstetrics department.

To analyse the association between positive total PEth levels in blood and several patient characteristics (age, ethnicity, gravidity, parity, reported alcohol consumption, gestational age, haemoglobin concentration and/or postal code) in pregnant women during their first visit to the obstetrics department.

To analyse the association between POPEth levels, PLPEth levels and DOPEth levels in blood and several patient characteristics (age, ethnicity, gravidity, parity, reported alcohol consumption, gestational age, haemoglobin concentration and/or postal code) in pregnant women during their first visit to the obstetrics department.

Study design

Prospective prevalence study.
All pregnant women that visit the outpatient obstetrics department of Erasmus MC and by whom routine laboratory testing is performed for the first time (new pregnant women), regardless of their gestational age, will be included anonymously in the study, unless opt-out. Analysis will be performed with means of rest material.

Study burden and risks

Minimal.

Contacts

Public
Erasmus MC

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Scientific
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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Pregnancy
First visit to the outpatient obstretics department
Vena puncture for routine care laboratory testing

Exclusion criteria

Age < 18 years

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	26-01-2016
Enrollment:	1000
Type:	Actual

Ethics review

Approved WMO Date:	21-12-2015
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

Approved WMO Date:	26-07-2016
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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	NL53549.078.15