EFfect of brEastfeeding on lipid profile and cardiovascular risk Markers In womeN with familial hypercholesterolemiA

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The aim of this study is to investigate the effects of breastfeeding on lipid profile and cardiovascular risk markers in women with familial hypercholesterolemia (FH). In addition, breast milk composition and the transfer of statins to breast milk...

Ethical review	Approved WMO
Status	Pending
Health condition type	Metabolic and nutritional disorders congenital
Study type	Observational invasive

Summary

ID

NL-OMON56956

Source
ToetsingOnline

Brief title
FH-FEMINA

Condition

- Metabolic and nutritional disorders congenital

Synonym
Familial hypercholesterolemia, hereditary high cholesterol

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: breastfeeding, cholesterol, Familial hypercholesterolemia, statin

Outcome measures

Primary outcome

Investigate the effects of breastfeeding on lipid profile in women with FH.

Secondary outcome

Investigate the composition of breast milk of women with FH and compare between

women with and without statin use.

Investigate the influence of breastfeeding on other cardiovascular risk markers

in women with FH (e.g. inflammation such as CRP).

Study description

Background summary

Familial hypercholesterolemia (FH) is a common (1:250) hereditary condition causing high cholesterol levels and an increased risk of premature cardiovascular disease. Lipid lowering therapy (LLT), e.g. statins, is contra-indicated in the conception, pregnancy and breastfeeding period. Due to these off-treatment periods, women with FH may accumulate a higher cholesterol burden at young age. Little is known how breastfeeding affects lipid profile and other cardiovascular risk markers in women with FH and to what extent statins transfer to breast milk. The insights from this study could provide recommendations for future care.

Study objective

The aim of this study is to investigate the effects of breastfeeding on lipid profile and cardiovascular risk markers in women with familial hypercholesterolemia (FH). In addition, breast milk composition and the transfer of statins to breast milk will be assessed in women with FH.

Study design

We will perform a prospective observational cohort study in which women will be followed up for one year, starting at the end of the pregnancy period up to 12 months post-partum or end of breastfeeding period.

Study burden and risks

The risk of participating is small. Participants only have a small increased risk of pain and hematomas from the blood drawings (and dried blood spot). An experienced nurse or member of the blood drawing location will perform the venapunction to minimize this chance.

Participants will have a maximum of 15 blood drawings during the 1 year follow-up depending on the duration of breastfeeding. The frequency and amount will not pose a health risk for the participant. Based on our pilot study, we expect participants will have less than 15 blood drawings. We observed an average breastfeeding duration of 3.6 months which would result in 8x blood drawings when participating in our study.
Women will receive the usual standard of care for FH as always.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Babies and toddlers (28 days-23 months)

Inclusion criteria

1) Women aged >= 18 years
2) Have a clinical (based on the Dutch Lipid Clinic Network score) or genetic diagnosis of FH.
3) Pregnant.
4) Have a sufficient command of the Dutch, Norwegian or English language.

Exclusion criteria

1) below 18 years of age.
2) Postmenopausal.
3) Use of contraception.
4) Underwent ovariectomy.
5) Not able or willing to give informed consent.

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-09-2024
Enrollment:	50
Type:	Anticipated

Ethics review

Approved WMO Date:	16-08-2024
Application type:	First submission
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
ClinicalTrials.gov	NCT05367310
CCMO	NL84345.078.23