

Effects of the diet on human milk composition.

Gepubliceerd: 14-06-2012 Laatste bijgewerkt: 18-08-2022

The quality of human milk shows an association with the women's diet and lifestyle.

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

Samenvatting

ID

NL-OMON29542

Bron

Nationaal Trial Register

Verkorte titel

Medidiet

Aandoening

Healthy parturient mothers

Ondersteuning

Primaire sponsor: Danone Research - centre for Specialised Nutrition

Overige ondersteuning: Danone Research - centre for Specialised Nutrition

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

1. Mothers' Diet Index;

2. Mother's anthropometry;

3. Mother's (non)-smoking status;

4. Mother's level of physical activity.

Toelichting onderzoek

Achtergrond van het onderzoek

The dietary intake of Italian women who have just given birth will be collected via questionnaire. Data on the women's lifestyle, living environment, anthropometry, and medical history will also be collected. The milk composition of those women and an association with the dietary habits and the other characteristics of the women will be assessed.

Doel van het onderzoek

The quality of human milk shows an association with the women's diet and lifestyle.

Onderzoeksopzet

Time points of the outcome: V1 (5-7 weeks after pregnancy).

Onderzoeksproduct en/of interventie

N/A

Contactpersonen

Publiek

Danone Research - Centre for Specialised Nutrition

Human Milk Research, Baby Nutrition Division

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Italian women aged between 25 and 40;
2. Given birth to term born babies;
3. Written informed consent;
4. Willingness and capability to comply with protocol requirements and procedures.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Alcohol abuse;
2. Underlying disease requiring medical intervention;
3. History of blood transfusion;
4. Use of drugs or pharmacologically active substances;
5. Presence of acute infection disease or neoplastic disease or any kind of weakening and debilitating conditions;
6. Mastitis, fungal infections of the nipple or areola;
7. Reactivation of herpes simplex (HSV) or varicella zoster infections in the mammary or thoracic region;
8. Presence of endocrinologic diseases, particularly diabetes mellitus;
9. Presence of metabolic diseases, particularly obesity;
10. Presence of chronic diseases: renal, cardiovascular, hypertension;

11. Elimination diet due to chronic allergic diseases or vegan;
12. Presence of one of the following autoimmune diseases: systemic lupus eritematosus, systemic scleroderma, colitis ulcerosa, Crohn's disease, celiac disease;
13. Participation in other clinical studies;
14. Women whose health condition, according to the investigator's judgment, could compromise the participation in the study.

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Factorieel
Toewijzing:	N.v.t. / één studie arm
Blinding:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland	
Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-07-2012
Aantal proefpersonen:	300
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies	
Datum:	14-06-2012
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL3321
NTR-old	NTR3468
Ander register	Danone Research : 31060 MD
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten

N/A