Long-term follow-up of children exposed in utero to low-dose aspirin for prevention of preterm birth, a follow-up of the APRIL trial

Gepubliceerd: 02-10-2020 Laatst bijgewerkt: 13-12-2022

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

Samenvatting

ID

NL-OMON21183

Bron
NTR

Verkorte titel
APRIL follow-up study

Aandoening

Prevention of preterm birth in multiple pregnancy

Ondersteuning

Primaire sponsor: Amsterdam UMC
Overige ondersteuning: AR&D grant

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

(neuro)development and behaviour

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale: Low-dose aspirin is frequently used in obstetric clinical practice for the prevention of pre-eclampsia and fetal growth restriction. There are no perinatal or maternal harms of aspirin use during pregnancy. However, long-term health data of children exposed to aspirin in utero is lacking.

Objective: To assess the long-term effect of in-utero exposure to low-dose aspirin compared to placebo on child (neuro)development, behavior and health.

Study design: Long-term follow-up of 4-year old children born to mothers from the APRIL trial who were randomized between low-dose aspirin (80 mg) and placebo. Study medication started between 8- and 16-weeks gestation and continued up to 36 weeks gestation or delivery, whichever came first.

Study population: All women that participated in the APRIL trial (n=406) and their children at four years corrected age.

Main outcomes: (neuro)development and behaviour.
Additional outcomes: mortality (perinatal death and infant death up to 4 years of age), child's growth and health related problems (i.e. information on surgery, medication use and hospital admissions).

Onderzoeksopzet

4 years

Onderzoeksproduct en/of interventie

Low dose aspirin

Contactpersonen

Publiek

Amsterdam UMC
Emilie van Limburg Stirum

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Wetenschappelijk

Amsterdam UMC
Emilie van Limburg Stirum

003120566740

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

All mothers and their child that participated in the APRIL trial. Mortality data of all children up to 4 years will be collected. Surviving children will be assessed at 4 years corrected age (ranging between 45 months and 51 months calculated from the expected date of delivery).

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

Women that withdraw their consent after randomization in the original APRIL trial. Women that did not gave consent to be approached for follow-up during the original APRIL trial.

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Dubbelblind
Controle:	Placebo

Deelname

Nederland
Status: Werving gestart

(Verwachte) startdatum:	01-07-2020
Aantal proefpersonen:	200
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Ja

Toelichting
n/a

Ethische beoordeling

Positief advies

Datum:	02-10-2020
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	NL8950
Ander register	METC AMC : W20_289 # 20.325

Resultaten

Samenvatting resultaten
n/a