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

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON21183

Source
NTR

Brief title
APRIL follow-up study

Health condition

Prevention of preterm birth in multiple pregnancy

Sponsors and support

Primary sponsor: Amsterdam UMC
Source(s) of monetary or material Support: AR&D grant

Intervention

Outcome measures

Primary outcome

(neuro)development and behaviour

Secondary outcome

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).

Study description

Background summary

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).

Study design

4 years

Intervention

Low dose aspirin

Contacts

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Eligibility criteria

Inclusion criteria

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).

Exclusion criteria

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.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-07-2020

Enrollment:	200
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Yes

Plan description
n/a

Ethics review

Positive opinion

Date:	02-10-2020
Application type:	First submission

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
NTR-new	NL8950
Other	METC AMC : W20_289 # 20.325

Study results

Summary results
n/a