

Quadruple-P follow-up

Gepubliceerd: 01-08-2021 Laatste bijgewerkt: 07-02-2024

To assess the long-term effects of in utero exposure to progesterone or a pessary on child (neuro)development and behaviour at 6 years of corrected age

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

Samenvatting

ID

NL-OMON26646

Bron

Nationaal Trial Register

Verkorte titel

QP FU

Aandoening

Women with short cervical length during mid-trimester, therefore having a higher risk on preterm birth

Ondersteuning

Primaire sponsor: None

Overige ondersteuning: None

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Child (neuro)development and behaviour disabilities

Toelichting onderzoek

Achtergrond van het onderzoek

Vaginal progesterone and a cervical pessary are both interventions to prevent preterm birth in high risk pregnancies. Thus far, beneficial or harmful effects of these interventions on long-term child health and development are not described, but number of literature is scarce. With this follow-up study, we intent to investigate if progesterone or a pessary is superior for the prevention of preterm birth considering child's health on the long term. This study is a follow-up study of the Quadruple-P trial; a multicentre, randomised clinical trial (NL42926.018.13, Eudractnumber 2013-002884-24) which randomises women with an asymptomatic midtrimester short cervix to daily progesterone or a pessary for the prevention of preterm birth. All children born to mothers who participated in the Quadruple-P study (n=628 singletons and n=332 multiples) will be eligible for follow-up at 4-6 years of corrected age. Children will be assessed using parental questionnaires. Primary outcomes are child (neuro)development and behavior. Secondary outcomes include child mortality, growth and general health. A composite of adverse child outcome will be compared between progesterone and pessary group reporting odds ratio and the corresponding 95% Confidence Interval. Analyses will be performed by intention to treat.

Doel van het onderzoek

To assess the long-term effects of in utero exposure to progesterone or a pessary on child (neuro)development and behaviour at 6 years of corrected age

Onderzoeksopzet

questionnaires will be filled in when children are 4 till 7 years of age

Contactpersonen

Publiek

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Wetenschappelijk

Amsterdam UMC, locatie AMC
Larissa van der Windt

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

children of women who have participated in the Quadruple-P study

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

Participants who did not give consent to be approached for follow-up
Participants who do not speak Dutch

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blinding:	Open / niet geblindeerd
Controle:	Actieve controle groep

Deelname

Nederland	
Status:	Werving gestart
(Verwachte) startdatum:	01-03-2021
Aantal proefpersonen:	600
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nee

Ethische beoordeling

Positief advies

Datum: 01-08-2021

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	NL9646
Ander register	METC AMC : W20_481 # 20.531)

Resultaten