

Quadruple-P follow-up

Published: 01-08-2021

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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

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

Summary

ID

NL-OMON26646

Source

NTR

Brief title

QP FU

Health condition

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

Sponsors and support

Primary sponsor: None

Source(s) of monetary or material Support: None

Intervention

Outcome measures

Primary outcome

Child (neuro)development and behaviour disabilities

Secondary outcome

Study description

Background summary

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.

Study objective

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

Study design

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

Contacts

Public

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Eligibility criteria

Inclusion criteria

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

Exclusion criteria

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

Study design

Design

Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL	
Recruitment status:	Recruiting
Start date (anticipated):	01-03-2021
Enrollment:	600
Type:	Anticipated

IPD sharing statement

Plan to share IPD: No

Ethics review

Positive opinion

Date: 01-08-2021

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	NL9646
Other	METC AMC : W20_481 # 20.531)

Study results