Follow-up of the PETRA (Pre-Eclampsie TRial Amsterdam) children at puberty: health, neurocognitive abilities, and behaviour

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Since this cohort is at risk for many developmental problems, further follow-up on this cohort is warranted. We especially want to examine growth, pubertal development, and the neurocognitive- and behavioural development. Since we have many...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Observational non invasive

Summary

ID

NL-OMON36864

Source
ToetsingOnline

Brief title
Follow-up of the PETRA (Pre-Eclampsie TRial Amsterdam) children at puberty

Condition

- Other condition

Synonym
intra uterine growth restriction

Health condition

bloeddruk, puberteitsontwikkeling, neurocognitieve ontwikkeling, gedrag

Research involving

Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: restgelden van subsidies verkregen voor eerder wetenschappelijk onderzoek

Intervention

Keyword: Follow-up, Health, Neurocognitive development, Puberty

Outcome measures

Primary outcome

Health development

• Height

• Weight

• Body mass index

• Head circumference

• Skin fold thickness: triceps, scapula, biceps, and suprailiac thickness

• Circumference of mid upper arm, waist and hip

• Pubertal development according to Tanner*s stadia, age of menarche

• Systolic and diastolic blood pressure (BP)

Neurocognitive- and behavioural development

• Intellectual development:

• Attention

• Executive functions

• Behaviour according to parents and child

Secondary outcome

Health questionnaire concerning the last 2 years

•Health problems; nature of problem; visit/treatment specialist; frequency of visit

•Medication: sort medication; frequency

•Surgical treatment

•Disabilities

Family questionnaire

•Birth date parents

•Parental weight

•Parental height

•Country of birth

•Highest educational level

•Current employment

•Other members of the family

Educational level of the child

• National educational achievement test (CITO test); domain scores language (taal), mathematics (rekenen-wiskunde), study abilities (studievaardigheden) and geography (wereld orientate), a total score and a standard score

• School advice after CITO test

• Current level of education and grade

• Extra support at school (rugzakje)

Study description

Background summary

Hypertensive disorders of pregnancy, like preeclampsia and HELLP (hemolysis, elevated liver enzymes and low platelet count) syndrome, are strongly associated to intra uterine growth restriction (IUGR). Children born growth restricted have an increase risk at several developmental domains, like problems with growth, cognitive abilities and behavioural problems. Less is known about the pubertal development, attention abilities and executive functions (higher order functions).
In the Academic Medical Center Amsterdam (AMC) and the VU Medical Center we have followed a cohort of children born to mothers that participated in the PETRA (Pre-eclampsia Eclampsia TRial Amsterdam). These mothers had severe and early onset hypertensive disorders of pregnancy. The majority of the children, 90%, had IUGR.
We have examined the PETRA children at age 3 months, 1 year, and 4.5 years. Follow-up at age 4.5 was performed in the outpatient clinic of the AMC. We found a normal cognitive- motor- and behavioural development in 54% of the participating children. There was catch-up growth, but the children were still smaller and especially lighter compared to Dutch reference curves. We also found that the degree of growth restriction at birth was strongly related to all growth scores.

Study objective

Since this cohort is at risk for many developmental problems, further follow-up on this cohort is warranted. We especially want to examine growth, pubertal development, and the neurocognitive- and behavioural development. Since we have many information of this cohort available, like for example the degree of IUGR, our cohort is very suited to examine the consequences of hypertensive disorders of pregnancy and IUGR on child development.

Objectives:
1. To assess the health of the PETRA cohort in puberty i.e. growth, fat distribution, pubertal development, and blood pressure in rest and also in response to a stressful event.

2. To assess the neurocognitive and behavioural development of the PETRA cohort at puberty; IQ, attention, executive functioning, and behaviour.

3. To assess to relation between health and neurocognitive and behavioural outcome of the PETRA cohort, both assessed at puberty.

3. To assess the relation of pubertic health, neurocognitive outcome and

behaviour of the PETRA cohort with pregnancy complications, and with growth and development at age 1 year and 4.5 years.

5. To assess growth changes from 4.5 to 12 years in relation to neurocognitive and behavioural changes from 4.5 to 12 years.

Study design

Design: Prospective cohort study
Duration: 3 years
Setting: The outpatient clinic of the Academic Medical Center Amsterdam

Study burden and risks

burden is negligible

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adolescents (12-15 years)
Adolescents (16-17 years)

Inclusion criteria

Study group: Children of the PETRA.
Control group: Age- and gender matched children born at term (>= 37 weeks gestational age) without growth restriction (>= 2500 grams) (either class mates or family).

Exclusion criteria

Study group: Only children from the PETRA are included.
Control group: Children born at a gestational age < 37 weeks, and or birth weight < 2500 grams, or children that are not age matched (> 1 year difference from corrected age of child in study group).

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Other

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	21-02-2013
Enrollment:	178
Type:	Actual

Ethics review

Approved WMO

Date:	07-01-2013
Application type:	First submission
Review commission:	METC Amsterdam UMC

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
CCMO	NL42097.018.12