Social and Cognitive development in pReterm born young AdulTS

Published: 15-10-2018
Last updated: 11-04-2024

Primary objective: to determine the association between social and cognitive performance of preterm-born young adults and their early motor repertoire up to 3 months after term.
Secondary objective: to describe the social and cognitive functioning...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Neonatal and perinatal conditions
Study type	Observational non invasive

Summary

ID

NL-OMON48916

Source
ToetsingOnline

Brief title
Socrates

Condition

- Neonatal and perinatal conditions
- Age related factors

Synonym
Prematurity, preterm birth

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Cognitive development, Infant, premature, Social development

Outcome measures

Primary outcome

Primary endpoint: Total IQ (measured by the Wechsler Adult Intelligence Scale, WAIS), with subdivision into verbal and performance IQ.

Secondary outcome

Secondary endpoints: neuropsychological development measured by a series of tests and questionnaires, anthropometry by assessment, and reported health-related behaviors, perceived health, social relations, social cognition, time spending, school or work performance and pain perception.

Study description

Background summary

When an infant is born, it is difficult to predict the outcomes on the various domains of development, particularly if risk factors for an abnormal development are present, such as preterm birth. It is known that preterm-born children experience more social and cognitive problems in comparison with the norm population. Much less is known, however, about their functioning at adulthood.

Study objective

Primary objective: to determine the association between social and cognitive performance of preterm-born young adults and their early motor repertoire up to 3 months after term. Secondary objective: to describe the social and cognitive functioning of preterm-born young adults compared with healthy controls.

Study design

Prospective longitudinal cohort study

Study burden and risks

At home, questionnaires will be filled in by the young adults regarding socio-demographic data (including general questions regarding socioeconomic status (SES), family composition, major life-events in the family, medical history, school and work performance, perceived health and pain perception), perceived behavioral and emotional problems, mental health, executive functioning, and signs of Attention Deficit Hyperactivity Disorder. This will take approximately 60 to maximally 90 minutes.
We will then invite the young adults to the UMCG. During that visit with a total time-span of 3 to maximal 3.5 hours including instructions and 2 short breaks of 15 minutes we will perform:
- Neuropsychological tests performed for intelligence (IQ), information processing speed and attention, executive functioning, (visual-spatial/verbal) memory and social cognition.
- A limited physical examination, including measurements of weight, length, head, waist and upper arm circumferences, blood pressure, and percentage body fat. For estimating body fat percentage, Bioelectrical Impedance Analysis (BIA) will be used.

Contacts

Public
Universitair Medisch Centrum Groningen

Hanzeplein 1
Groningen 9713GZ
NL
Scientific
Universitair Medisch Centrum Groningen

Hanzeplein 1
Groningen 9713GZ
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Patient group:
Gestational age < 34 weeks
Written informed consent of participating young adults
Control group:
Written informed consent of participating young adults

Exclusion criteria

Patient group:
None
Control group:
Prematurity

Study design

Design

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

Primary purpose: Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	14-02-2019
Enrollment:	164

Type:	Actual

Ethics review

Approved WMO Date:	15-10-2018
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	06-02-2019
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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	NL66718.042.18