

Early Intervention Project: a multi-level evaluation of early (physiotherapeutical) intervention in infants at high risk for the development of cerebral palsy

Submission date 19/12/2005	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 19/12/2005	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 17/06/2019	Condition category Nervous System Diseases	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

NTR361

Study information

Scientific Title

Early Intervention Project: a multi-level evaluation of early (physiotherapeutical) intervention in infants at high risk for the development of cerebral palsy

Acronym

VIP

Study objectives

Intervention with the recently developed COPCA method improves developmental outcome at 6 and 18 months more than traditional types of early physiotherapeutical intervention.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics approval received from the local medical ethics committee

Study design

Randomised active controlled parallel group trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

Health condition(s) or problem(s) studied

Cerebral palsy (cerebral palsy)

Interventions

Intervention: COPCA = COPing with and CARing for infants with neurological dysfunction.
Control: traditional types of early physiotherapeutical intervention.

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

Neuromotor condition.

Secondary outcome measures

1. Pediatric Evaluation of Disability Inventory (PEDI)
2. KID-N and Bayley MDI
3. Parameters of postural control
4. NVOS
5. MPOC

Overall study start date

01/03/2003

Completion date

29/02/2008

Eligibility

Key inclusion criteria

Infants who have been referred to the Neonatal Intensive Care Unit (NICU) of the Beatrix Children's Hospital of the University Medical Centre Groningen (UMCG) and who have definitely abnormal general movements at the corrected age of 3 months.

Participant type(s)

Patient

Age group

Child

Sex

Both

Target number of participants

40

Total final enrolment

46

Key exclusion criteria

1. Presence of severe congenital anomaly
2. Inappropriate parental understanding of the Dutch language

Date of first enrolment

01/03/2003

Date of final enrolment

29/02/2008

Locations

Countries of recruitment

Netherlands

Study participating centre

University Medical Center Groningen

Groningen

Netherlands

9700 RB

Sponsor information

Organisation

University Medical Centre Groningen (UMCG) (Netherlands)

Sponsor details

Beatrix Children's Hospital

P.O. Box 30001

Groningen

Netherlands

9700 RB

Sponsor type

Hospital/treatment centre

Website

<http://www.umcg.nl/azg/nl/english/azg/>

ROR

<https://ror.org/03cv38k47>

Funder(s)

Funder type

Charity

Funder Name

Johanna Children's Fund (Johanna Kinderfonds) (The Netherlands)

Funder Name

The Foundation Fund Gavere (Stichting Fonds de Gavere) (The Netherlands)

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date**Individual participant data (IPD) sharing plan****IPD sharing plan summary**

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/09/2011		Yes	No
Results article	results	01/04/2019	17/06/2019	Yes	No