ISRCTN85728836 https://doi.org/10.1186/ISRCTN85728836

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	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 19/12/2005	**Overall study status** Completed	
Last Edited 17/06/2019	**Condition category** Nervous System Diseases	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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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 parese (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 Unversity 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