ISRCTN12148268 https://doi.org/10.1186/ISRCTN12148268

Effect of early physiotherapy in children born preterm

Submission date
13/12/2024

Recruitment status
No longer recruiting

Registration date
18/12/2024

Overall study status
Completed

Last Edited
19/12/2024

Condition category
Pregnancy and Childbirth

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Every year, 3000 infants are born preterm in Norway, or 6% of all births. Thanks to modern medicine, 90% survive. Studies of previous generations of preterm children show a high risk of adverse outcomes, amongst other motor difficulties and reduced quality of life, which might persist to adult age. Early interventions are thought to be important to promote coping and participation. In 2010-14, a study was carried out in three university hospitals in Norway. Infants born before 32 weeks' gestation received either early physiotherapy or standard care. There was an immediate effect with better motor function in the intervention group, but at two years there was no difference between the groups. However, motor function may not be stable throughout childhood, and assessment at two years may be too early to determine long-term effects. This study will determine the effect of the intervention at 7-10 years and examine whether motor function has consequences for the child’s level of physical activity, mental health and quality of life. Data have already been collected. User representatives have contributed to the planning of the study, which ensures the relevance for preterm children and their families. The study complies with the strategic priorities of Central Norway Regional Health Authorities by involving multidisciplinary and clinically relevant patient-centered research. The aim of the study is to explore the long-term effect of early physiotherapy intervention and the interplay between motor function, physical activity, mental health and quality of life.

Who can participate?
Children aged from 7 to 10 years old, one group born preterm who have participated in a study of early intervention, and another group of children born at term.

What does the study involve?
Even though the quality of intensive care for infants born preterm has improved during the recent decades and the survival of the most immature infants has increased, many will still be suffering from long-term adverse outcomes. The study involves a clinical follow-up at 7-10 years of age with assessments of motor function, physical activity and quality of life in children born preterm and at term. The preterm-born children had previously been participants in a multicenter, randomized control study of early intervention. Data collection was carried out between May 2020 and September 2022

What are the possible benefits and risks of participating?
This study is expected to provide new knowledge beneficial to individuals born very preterm and their families as well as health and educational professionals. The results from the study might help clinicians decide whether to implement early physiotherapy for children born very preterm. During childhood, preterm birth has public health implications, related to paediatric healthcare resources, family support, and school education. The range of developmental difficulties for children born preterm is diverse, but they all may significantly affect the quality of life. Knowledge about associations between motor function, physical activity, mental health and quality of life has implications also for primary health care as well as school and educational systems. Moreover, the results can guide public health policy relevant to both community and specialised health care services. The study will provide important contributions to paediatric medicine, physiotherapy, occupational therapy, movement sciences, psychology and mental health disciplines for children and adolescents. Dissemination and implementation of results will contribute to identifying the multidisciplinary needs of preterm birth. The achievements will provide the basis for further follow-up research on preterm birth.
Participants are offered a thorough clinical examination, receive medically relevant feedback and are referred to appropriate health services if needed. All methods are non-invasive and entail a very low risk of injury or adverse events.

Where is the study run from?
The Norwegian University of Science and Technology and St Olavs Hospital

When is the study starting and how long is it expected to run for?
June 2018 to August 2022. Data collection started in May 2020.

Who is funding the study?
The study was supported by grants from The Central Norway Regional Health Authority (RHA - Helse Midt-Norge)

Who is the main contact?
Tordis Ustad (Project leader), tordis.ustad@ntnu.no
The main contact is Kari Anne I. Evensen, Professor at NTNU, karianne.i.evensen@ntnu.n

Contact information

Type(s)
Public, Principal investigator

Contact name
Mrs Tordis Ustad

ORCID ID
https://orcid.org/0000-0001-9668-6905

Contact details
IKOM, NTNU
Postboks 8900, Torgarden
Trondheim
Norway

7491
+47 99095103
tordis.ustad@ntnu.no

Type(s)
Scientific

Contact name
Mrs Kari Anne I. Evensen

ORCID ID
https://orcid.org/0000-0002-0129-0164

Contact details
IKOM, NTNU
Postboks 8900, Torgarden
Trondheim
Norway
7491
+47 97733635
karianne.i.evensen@ntnu.no

Additional identifiers

Protocol serial number
2019/2833/SISO

Study information

Scientific Title
Motor function, mental health, and quality of life in children born very preterm: A follow-up of a randomized controlled trial.

Acronym
NOPPI 2

Study objectives
Children born very preterm and exposed to intervention have slightly better motor function at 7-10 years old than children receiving standard care. Both preterm groups have poorer motor function, mental health, and quality of life, and are less physically active compared to a control group of children born at term.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 10/09/2019, The Regional Committee for Medical and Health Research Ethics North in Norway (REC North) (UiT Norges arktiske universitet, Postboks 6050 Langnes, Tromsø, 9037, Norway; +47 77645232; rek-nord@asp.uit.no), ref: 10013

Primary study design
Observational

Study design
Long-term follow-up of a randomized controlled trial on effect of early physiotherapy for children born very preterm.

Study type(s)
Diagnostic, Prevention, Quality of life, Efficacy

Health condition(s) or problem(s) studied
Health and well-being of children born very preterm at 7 -10 years of age.

Interventions
The study involves a clinical follow-up at 7-10 years of age with assessments of motor function, physical activity and quality of life in children born preterm and at term. The preterm-born children had previously been participants in a multicenter, randomized control study of early intervention. Data collection was carried out between May 2020 and September 2022

Intervention Type
Other

Primary outcome(s)
Motor function is measured using the Movement Assessment Battery for Children – second edition (Movement ABC-2), the High-level Mobility Assessment Tool, the Grooved Pegboard Test and the Trail Making Test-5 at one timepoint

Key secondary outcome(s)
1. Physical Activity measured using a Tri-axial accelerometer Axivity AX3 for a period of 7 days when the child was 7 to 10 years old
2. Grip strength measured using a handheld dynamometer at one timepoint when the child was 7 to 10 years old
3. Walking distance has been measured using a 2-minute walk test at one timepoint when the child was 7 to 10 years old
4. Mental health and quality of life measured using the ASEBA Child Behaviour Checklist and KIDSCREEN-27, at one timepoint when the child was between 7 to 10 years old

Completion date
25/08/2022

Eligibility

Key inclusion criteria
1. Children born between 24 and 32 weeks gestational age, in 2010 to 2014, having participated in a study of early intervention
2. Term born children

Participant type(s)
Healthy volunteer, Patient

Healthy volunteers allowed
No

Age group
Child

Lower age limit
7 Years

Upper age limit
10 Years

Sex
All

Total final enrolment
175

Key exclusion criteria
1. Using walking aids
2. Not able to walk 20 meters independently

Date of first enrolment
19/05/2020

Date of final enrolment
25/08/2022

Locations

Countries of recruitment
Norway

Study participating centre
St. Olavs Hospital
Olav Kyrres gate 17
Trondheim
Norway
7030

Study participating centre
University Hospital of North Norway
Hansine Hansens veg 67
Tromsø
Norway
9019

Study participating centre
Oslo University Hospital, Ullevål
Kirkeveien 166
Oslo
Norway
0450

Sponsor information

Organisation
Norwegian University of Science and Technology

ROR
https://ror.org/05xg72x27

Funder(s)

Funder type
Government

Funder Name
Helse Midt-Norge

Alternative Name(s)
Central Norway Regional Health Authority

Funding Body Type
Government organisation

Funding Body Subtype
Local government

Location
Norway

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are stored in a non-publicly available repository (https://data.tsd.usit.no)

The datasets generated during and /or analysed during the current study will be available upon reasonable request from Kari Anne I. Evensen, karianne.i.evensen@ntnu.no

IPD sharing plan summary

Stored in non-publicly available repository, Available on request