ISRCTN86323684 https://doi.org/10.1186/ISRCTN86323684

The EPICure2 Study: educational and health outcomes at 11 years of age following extremely preterm birth

Submission date
14/11/2016

Recruitment status
No longer recruiting

Registration date
30/11/2016

Overall study status
Completed

Last Edited
29/10/2021

Condition category
Pregnancy and Childbirth

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
The national EPICure studies are concerned with the long term outcomes of babies who were born extremely premature (EP). EP births are only a small proportion of total births but they use a high proportion of resources in the newborn period, many needing 10 weeks or more intensive care. The high proportion of survivors with developmental problems is often highlighted in the press. The high risk of death or an impaired outcome is often used as a reason for not providing active support for these children. In 2006 a group of children born at <27 weeks of gestation (14 weeks or more before normal 'full term') were recruited and showed increased survival without impairment at 24 and 25 weeks of gestation compared with a similar, older study, which was carried out with children born in 1995. Of the children born in 2006, fewer infants at 3 years were found to have moderate to severe cerebral palsy (a condition that affects muscle control and movement) and had higher developmental scores when assessed. Because healthcare professional are continually trying to improve care, it is important to know that these important outcomes are improving. The aim of this study is to assess the progress of this important group of children at 11 years of age, to determine whether the early advantages found at three years of age have continued.

Who can participate?
Children who were born between 22-26 weeks gestation (pregnancy) whose mothers lived in London and Leicester and their nearby areas and children of the same age who were born at full term.

What does the study involve?
Children are visited either in school or at home and perform the assessment over the course of one school day. This involves completing a range of tests of mental function, educational ability and heart and lung assessments. Parents and teachers are also asked to fill in a number of questionnaires. All children have the same assessments and the results achieved by the extremely preterm children are compared to those of classmates.

What are the possible benefits and risks of participating?
Parents benefit from receiving test results from their children which can be used to discuss progress and support at school with their teachers. Any health issues identified are also reported to parents so that these issues can be discussed with the family doctor. There is a small risk that children may cough during lung function tests but often they are able to breathe easier following the medicine.

Where is the study run from?
The study is run from UCL Elizabeth Garret Anderson Institute for Women's Health and takes place in the community (UK)

When is the study starting and how long is it expected to run for?
June 2016 to July 2018

Who is funding the study?
Medical Research Council (UK)

Who is the main contact?
Dr Laura McCormack
epicure@ucl.ac.uk

Study website
http://epicure.ac.uk

Contact information

Type(s)
Public

Contact name
Dr Laura McCormack

Contact details
The EPICure Studies
University College London Institute for Women's Health
74 Huntley Street
London
United Kingdom
WC1E 6AU
+44 20 3108 2045
epicure@ucl.ac.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
v1 August 2016

Study information

Scientific Title
The EPICure Studies: Outcome at 11 years for a national cohort of births between 22 and 26 weeks of gestation in England in 2006

Acronym
EPICure2@11

Study objectives
The aim of the study is to perform a multilevel study of the 1040 children identified in EPICure2 to determine changes in outcome since 1995 using a geographical sample in two geographic regions with assessments taking place in schools with classmates as controls (including 300 EP children and up to 300 controls).

Ethics approval required
Old ethics approval format

Ethics approval(s)
UCL Research Ethics Committee, 30/01/2017, ref: 10175/001

Study design
Longitudinal national cohort study

Primary study design
Observational

Secondary study design
Longitudinal study

Study setting(s)
School

Study type(s)
Other

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Birth between 22 and 26 weeks of gestation

Interventions
Children will be assessed in their school environment using a range of neuropsychological and education tests, and cardiorespiratory assessments over one school day. Information will also be sought by parental and teacher questionnaires, and a structured interview with parents. The

attainments of the index extremely preterm cohort will be compared to that of classmates recruited for this study.

Intervention Type
Other

Primary outcome measure
IQ is measured using The Kaufmann-ABC (second edition) at 11 years of age.

Secondary outcome measures
1. Educational attainment is measured using teacher questionnaire, direct assessment (WIAT-II UK) and the results of national attainment tests at Key Stage 2
2. Behavioural outcomes will be measured using the Strengths and Difficulties Questionnaire, supplemented with the du Paul RS-IV scale for attentional problems and the Social Communication Questionnaire, which will be combined with the results of a post assessment parental interview using the Development and Wellbeing Assessment
3. Lung function measured using spirometry, exercise capacity (incremental walk test and 24h activity monitoring and clinical history
4. Blood pressure and augmentation index are measured using conventional blood pressure measurements and Doppler circulation assessment respectively

Overall study start date
01/06/2016

Completion date
31/07/2018

Eligibility

Key inclusion criteria
1. Birth during 2006
2. Born at 22-26 weeks of gestation
3. Mother resident in England

Participant type(s)
Patient

Age group
Child

Sex
Both

Target number of participants
1040 children

Total final enrolment
200

Key exclusion criteria

1. Having moved outside the UK
2. Family has withdrawn from the study

Date of first enrolment
01/01/2017

Date of final enrolment
31/07/2018

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
UCL Elizabeth Garret Anderson Institute for Women's Health
Huntley Street
London
United Kingdom
WC1E 6AU

Sponsor information

Organisation
University College London

Sponsor details
Joint Research Office
Gower Street
London
England
United Kingdom
WC1E 6BT

Sponsor type
University/education

ROR
https://ror.org/02jx3x895

Funder(s)

Funder type
Research council

Funder Name
Medical Research Council

Alternative Name(s)
Medical Research Council (United Kingdom), UK Medical Research Council, MRC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Planned publication in high impact peer review journal(s) in July 2019 and dissemination in national and international research meetings.

Intention to publish date
31/07/2019

Individual participant data (IPD) sharing plan
The current data sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		27/01/2021	29/10/2021	Yes	No
Results article	sleep disturbance results	14/07/2021	29/10/2021	Yes	No