

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	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 30/11/2016	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 29/10/2021	Condition category Pregnancy and Childbirth	<input type="checkbox"/> 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

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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