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Can 3D photography at birth help to detect prenatal alcohol exposure?

Submission date 04/01/2018	**Recruitment status** No longer recruiting	[X] Prospectively registered [ ] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [ ] Record updated in last year
Registration date 09/04/2018	**Overall study status** Completed	
Last Edited 07/04/2022	**Condition category** Other	

Plain English summary of protocol

Background and study aims
Prenatal alcohol exposure occurs when a woman drinks while pregnant. The aim of this study is to find out whether 3D photography and cranial (head) ultrasound imaging can detect craniofacial changes caused by prenatal alcohol exposure in newborn infants.

Who can participate?
Caucasian mothers and their babies

What does the study involve?
Mothers are asked to complete a questionnaire about their alcohol consumption before and during pregnancy. This questionnaire - which should take no longer than 5-10 minutes to complete - stays completely anonymous. The researcher then takes photographs of the baby using ordinary 2D and specialist handheld 3D cameras.

What are the possible benefits and risks of participating?
Participants contribute to medical research which may allow earlier diagnosis of babies with fetal alcohol syndrome disorders (FASD). There are no additional risks compared with normal medical care.

Where is the study run from?
1. The Royal Sussex County Hospital Maternity Wards, Brighton (UK)
2. The One Stop Clinic (a specialist clinic for pregnant mothers with substance/alcohol misuse), Brighton (UK)
This study is not open to recruitment by other centres

When is the study starting and how long is it expected to run for?
July 2017 to May 2019

Who is funding the study?
National Institute for Alcohol Abuse and Alcoholism (NIAAA), National Institutes of Health (USA) through the CIFASD consortium

Who is the main contact?
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Contact information

Type(s)
Scientific

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Public

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Additional identifiers

EudraCT/CTIS number

IRAS number
241498

ClinicalTrials.gov number

Secondary identifying numbers

IRAS 241498

Study information

Scientific Title
Comparing 2D and 3D photography using computerised analysis for earlier detection of craniofacial changes in newborn infants with and without prenatal alcohol exposure

Study objectives
3D photography and cranial ultrasound imaging in the newborn infant can detect prenatal alcohol exposure.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 01/05/2018, South Central - Berkshire Research Ethics Committee (Bristol REC Centre, Whitefriars, Level 3, Block B, Lewins Mead, Bristol, BS1 2NT, UK; +44 (0)207104 805; berkshire.rec@hra.nhs.uk), ref: 18/SC/0211

Study design
Single-centre observational cross sectional study

Primary study design
Observational

Secondary study design
Cross sectional study

Study setting(s)
Hospital

Study type(s)
Screening

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

Health condition(s) or problem(s) studied
Prenatal alcohol exposure

Interventions
Babies from the One Stop Clinic who have been exposed to significant levels of alcohol during pregnancy will be recruited to the study by the Chief Investigator. Consent will be obtained directly from the mother by the Chief Investigator using a different consent form and information sheet. It is estimated that 10-20 babies will be recruited per year from the clinic.

As part of the normal clinical pathway, these babies already receive a cranial ultrasound and 2D photography routinely within the first few weeks after birth. The only difference involvement in

the study entails is inclusion of 3D photography in addition to the routine 2D photographs. This will be saved in a file with a unique study id number. The data concerning alcohol consumption in pregnancy will be abstracted from the clinical notes by the chief investigator. The cranial ultrasound which has been performed for clinical reasons will be anonymised using specialist software. These will be stored with same unique id number.

These anonymous data images on both the alcohol and non-alcohol exposed groups will be transferred to the team at the Big Data Unit at Oxford University for further detailed 3D analysis. The images will undergo automated landmark annotation using curl, groove and twist alignment to develop automated algorithms combining surface curvature and feature detection. For initial screening this should allow a single numerical estimate of risk. Validation will come from comparison with large databases of controls and individuals diagnosed with FAS, and showing where an individual fits along the continuum between normal and full FAS features. As 3D imaging remains expensive, there will also be investigation of the comparison of 2D and 3D images to look at discriminatory performance between the two modalities. Software will be developed which may allow the use of hand-held mobile digital devices to use in screening.

Intervention Type
Other

Primary outcome measure
1. Facial morphology, measured by 3D photography at birth
2. Brain size, measured by cranial ultrasound at birth

Secondary outcome measures
1. Facial morphology, measured by 2D photography at birth
2. Prevalence of alcohol consumption in pregnancy, measured by questionnaire after birth
3. Length, birth weight and head circumference of newborn babies, measured by tape measure and scales at birth

Overall study start date
01/07/2017

Completion date
31/05/2019

Eligibility

Key inclusion criteria
1. Caucasian
2. 34-42 weeks gestation
3. Born in Brighton

Participant type(s)
Patient

Age group
Neonate

Sex

Both

Target number of participants
240

Total final enrolment
761

Key exclusion criteria
1. Either or both parents non-caucasian
2. Known congenital dysmorphic syndrome
3. Unresolved facial injury resulting from obstetric trauma
4. Fetal valproate exposure or fetal toluene exposure (very rare, but these have some overlapping facial characteristics)

Date of first enrolment
19/06/2018

Date of final enrolment
18/06/2019

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Royal Sussex County Hospital
Eastern Road
Brighton
United Kingdom
BN3 6BE

Sponsor information

Organisation
Brighton & Sussex University Hospitals NHS Trust

Sponsor details
Royal Sussex County Hospital
Brighton

England
United Kingdom
BN44 3QB

Sponsor type
Hospital/treatment centre

Website
www.bsuh.nhs.uk

Funder(s)

Funder type
Government

Funder Name
National Institute for Alcohol Abuse and Alcoholism (NIAAA), National Institutes of Health (USA) through the CIFASD consortium

Results and Publications

Publication and dissemination plan
Additional documents will be available from the Chief Investigator on request. Publication through presentation at conferences and scientific journals

Intention to publish date
01/06/2022

Individual participant data (IPD) sharing plan
The 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?
HRA research summary			26/07/2023	No	No