

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

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| Submission date 04/01/2018 | Recruitment status No longer recruiting | <input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol |
| Registration date 09/04/2018 | Overall study status Completed | <input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results |
| Last Edited 07/04/2022 | Condition category Other | <input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year |

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)

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Additional identifiers

Integrated Research Application System (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

Study type(s)

Screening

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(s)

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

Key secondary outcome(s)

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

Completion date

31/05/2019

Eligibility

Key inclusion criteria

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

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Neonate

Sex

All

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

United Kingdom

England

Study participating centre

Royal Sussex County Hospital

Eastern Road

Brighton

United Kingdom

BN3 6BE

Sponsor information

Organisation

Brighton & Sussex University Hospitals NHS Trust

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

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 |