ISRCTN14852287 https://doi.org/10.1186/ISRCTN14852287

Evaluation of non-invasive fingerprinting methods for healthcare recording in newborns and infants

Submission date
16/03/2022

Recruitment status
No longer recruiting

Registration date
25/03/2022

Overall study status
Completed

Last Edited
22/05/2023

Condition category
Other

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

Plain English summary of protocol

Background and study aims
Biometrics is the measurement and statistical analysis of people's unique physical and behavioral characteristics. The technology is mainly used to identify individuals based on these characteristics. Although there are many validated technologies to recognize adults, these technologies have been ineffective in newborns and young children. The present work describes the development and clinical testing of a fingerprint capture system designed for biometric recognition of newborns and young children for vaccination and clinical follow-up. This study aimed to test the new system in a newborn ward and immunization clinic at an urban hospital in Baja California, Mexico.

Who can participate?
Healthy infants aged less than 35 weeks

What does the study involve?
Prototypes of a biometric device are used to capture several images of an infant’s finger, foot, and/or hand prints. The study team may take photos and videos of the interactions. Parents /guardians will be asked to sign a separate consent to allow the team to record and/or photograph the infant’s movements.

What are the possible benefits and risks of participating?
Participation in this study will not involve any physical risks or discomforts. There is the risk of loss of confidentiality due to the child’s participation in this study. To minimize this risk, the team will assign each participant a study ID number and this will be used rather than the parent /guardian or child’s name.
Because this is a research study, there may be some unknown risks that are currently unforeseeable. Participants will be informed of any significant new findings. There is no direct benefit to the child participating in this study. The investigators, however, may learn more about biometric identification of infants that will be very important to children’s health around the world.

Where is the study run from?
UC San Diego (USA)

When is the study starting and how long is it expected to run for?
July 2015 to December 2020

Who is funding the study?
Bill and Melinda Gates Foundation (USA)

Who is the main contact?
Dr Eliah Aronoff-Spencer
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Contact information

Type(s)
Principal Investigator

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
BMGF OPP1159073

Study information

Scientific Title
Biometric recognition of newborns and young children for vaccinations and health care using non-contact fingerprinting: a non-randomized prospective clinical trial

Study objectives
Reliable infant (0-12 months) biometric identification is critical for effective healthcare yet has historically proven difficult to carry out. While the fingerprint is completed at around 4 months of gestation, accurate and reliable infant fingerprinting has posed significant problems over adult identification in many settings. This study is testing a device developed using principles of human-centered design to reliably capture and identify infant fingerprints.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 09/03/2015, University of California San Diego (UCSD) Human Research Protections Program (9500 Gilman Drive, La Jolla, CA 92093, USA; +1 (0)858 657 5100; hrpp@ucsd.edu), ref: 151400

Study design
Observational cohort study

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
Hospital

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
Biometric recognition of newborns and infants

Interventions
Participating parents are consented and enrolled. Fingerprints from each infant finger are captured using a non-contact imaging device. Multiple images are taken for each finger. Enrollment of fingers occurs on the first visit and takes 10-20 minutes. On subsequent visits the child’s finger is again scanned multiple times. Matching and processing are carried out retrospectively after encounter completion.

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Not applicable

Primary outcome measure
Enrollment goal reached, assessed using a target of 500 participants - consented parents and at least one participant encounter between 01/01/2018 and 31/12/2020

Secondary outcome measures
1. Failure to enrol rate, assessed using an image quality cutoff score and defined as no fingers with images of quality equal to or greater than this threshold from any image taken at time of encounter
2. Detection error tradeoff, assessed using standard methods for calculation of true positive and negative versus false positive and negative rates to determine thresholds optimizing sensitivity and specificity using data calculated after session encounters
3. Identification rates assessed using comprehensive match characteristics method ranking an individual match across many participants at 0-720 days time between enrollment and identification

Overall study start date
06/07/2015

Completion date
31/12/2020

Eligibility

Key inclusion criteria
1. Age minimum 34 weeks gestational age up to 1 year since birth
2. Male or female
3. Any ethnic background
4. Health status: well
5. Available for a minimum of two visits (to allow repeat identification)

Participant type(s)
Healthy volunteer

Age group
Neonate

Sex
Both

Target number of participants
500

Total final enrolment
494

Key exclusion criteria

1. Infants older than 6 months of age
2. Active health issues
3. Trauma or parental concerns

Date of first enrolment
01/01/2018

Date of final enrolment
31/12/2019

Locations

Countries of recruitment
Mexico

Study participating centre
General Hospital of Tijuana
Department of Research
Centenario 10851
Zona Urbana Rio, Tijuana
Mexico
22000

Study participating centre
Grupo Pediatrico de Tijuana / Dr Enrique Chacon-Cruz
Germán Gedovius 10489
Zona Urbana Rio, Tijuana
Mexico
22010

Sponsor information

Organisation
Bill & Melinda Gates Foundation

Sponsor details
500 5th Ave. N
Seattle
United States of America
98109
+1 (0)2067093100
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Sponsor type
Charity

Website
http://www.gatesfoundation.org/

ROR
https://ror.org/0456r8d26

Funder(s)

Funder type
Charity

Funder Name
Bill and Melinda Gates Foundation

Alternative Name(s)
Bill & Melinda Gates Foundation, Gates Foundation, BMGF, B&MGF, GF

Funding Body Type
Government organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
United States of America

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal

Intention to publish date
01/04/2022

Individual participant data (IPD) sharing plan
All reasonable efforts will be made to keep the neonate’s personal information confidential. The video recordings will be used for device development and destroyed at the completion of the study. The researchers will not collect any other protected health information (PHI) or any personal information that might lead to individual identification. No PHI will be used in any reports or publications about this study. There is the risk of loss of confidentiality due to disclosure is required by law or through University of California San Diego organizations that may inspect and/or copy research records for quality assurance and data analysis.

Several methods will be used to ensure confidentiality. Patient identifiable information will not be recorded in the study database or in any subsequent analysis. All collected data will be recorded with a sequential patient identification number. The key linking study ID to identifiable information will be retained in a password-protected file and/or in a locked location, accessible only to the research team and separate from other study data. The study database will be password protected and stored on a secure server. The information will not be disclosed without consent except where required by law. The results of the study when published will have no patient identifying PHI. Videos will also be maintained in a password-protected file and/or in a locked location accessible only to the research team.
Patients will be assigned a study ID number which will be used for study purposes. The key linking study ID numbers to identifiable information will be kept in a password-protected file and /or in a locked location separate from all other study data. Upon completion of the publication of findings, the key that links PHI data to subject ID will be destroyed. The study database will be stored on a password-protected computer file on a secure server with access restricted to study members. No PHI will be presented or published. PHI will be destroyed after the study /manuscript is complete and no further analysis will be performed.

IPD sharing plan summary

Stored in non-publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		29/12/2022	22/05/2023	Yes	No