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NewbornTime – Improved newborn care based on video and artificial intelligence

Submission date
16/02/2023

Recruitment status
Recruiting

Registration date
22/02/2023

Overall study status
Ongoing

Last Edited
09/03/2023

Condition category
Pregnancy and Childbirth

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims
Approximately 3-8% of all newborns require time-critical resuscitation. NewbornTime will produce a timeline describing events and activities performed on a newborn. Accurate time of birth will be detected using artificial intelligence (AI) models from thermal videos collected in the delivery room. Activity recognition will be performed using AI in the form of deep convolutional neural networks (CNN) on thermal and visual light video from the resuscitation. The system will be designed to recognize multiple time-overlapping activities. Care will be given to make the AI models robust, reliable, general, and adaptive for use in different hospitals and settings. The timelines will be used to evaluate compliance with guidelines and identify successful resuscitation activity patterns. It can further be useful in a de-briefing and quality improvement tool.

Who can participate?
All mothers giving birth at Stavanger University hospital and their newborns

What does the study involve?
Improve newborn resuscitation based on video and artificial intelligence.

What are the possible benefits and risks of participating?
The long-term benefit of participating is that the system can provide new knowledge and a solution for quality improvement. This is an observational study and does not pose any risk to the mother or newborn. Data are stored encrypted and with strict access control.

Where is the study run from?
The project is a collaboration between the University of Stavanger (UiS), Stavanger University Hospital (SUS), Laerdal Medical and BitYoga. UiS, SUS and Laerdal have long experience in collaborative research on newborn care. They have documented promising results in detecting activities using resuscitation videos from a hospital in Tanzania. In NewbornTime the data collection will be performed at SUS. BitYoga and Laerdal will ensure smart GDPR-compliant data contracts and data platforms. UiS will develop site-adaptive AI methods for activity recognition in video. The project has been recommended by Sikt – Norwegian Agency for Shared Services in Education and Research, formerly known as NSD (number 816989).

When is the study starting and how long is it expected to run for?
September 2020 to August 2025

Who is funding the study?
1. Norwegian Research Council (NRC) (project number 320968) (Norway)
2. Helse Vest (Norway)
3. Fondation Idella (Liechtenstein)
4. Helse Campus UiS (Norway)

Who is the main contact?
Prof Kjersti Engan, kjersti.engan@uis.no (Norway)
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Study website
https://www.uis.no/newborntime

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
NRC 320968

Study information

Scientific Title
NewbornTime – Improved newborn care based on video and artificial intelligence

Acronym
NewbornTime

Study objectives
The rationale for the study is to improve newborn care using artificial intelligence (AI) for activity and event recognition taken from thermal and visual light videos in the time both during and immediately after birth

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 09/03/2021, Regional ethical committee west (REK Vest) (Haukelandsveien 28, 5009 Bergen, Norway; +47 55589711; rek-vest@uib.no), ref: 222455

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
Patient information material can be found at https://www.uis.no/en/newborntime/participant

Health condition(s) or problem(s) studied
Newborn resuscitation

Interventions
This study investigates newborn resuscitation because birth asphyxia is a primary cause of death in newborns, and immediate resuscitation of the newborn is crucial to reduce the risk. Currently, there exists no method to automatically record the time of birth or provide objective measurements for the series of activities that took place at a newborn resuscitation.

The NewbornTime project aims to utilize video recordings from births and newborn resuscitations to develop an artificial intelligence (AI)-based system, NewbornTimeline, for automatic timeline generation of birth and resuscitation activities. The timeline is put together from the time of birth and the start and stop times of resuscitation activities if any until the end of the resuscitation episode. The timeline documents what events took place so that healthcare professionals can learn; it can detect deviations and it can identify areas where there is a need for better routines or training. Resuscitation activities include stimulation, clearing airways and performing bag-mask ventilation.

The system input will be based on thermal video from the delivery room and visual light and thermal video from the resuscitation table. By using artificial intelligence and video processing, we will develop algorithms to automatically and accurately detect the time of birth and resuscitation activities.

The time of birth will be manually marked by a nurse by pressing a “Baby born” button on an iPad used for the research project. The resuscitation activities will be assessed retrospectively by a medical doctor watching the visual light videos and marking the start and stop of all the relevant events and activities, like ventilation, stimulation, suction, and chest compression.

Intervention Type
Other

Primary outcome measure
NewbornTimeline will be evaluated through the following outcome variables:
1. Time of birth measured using the artificial intelligence-based judgement of the video recording of the labor by a thermal camera and manually recorded time as ground truth at the time of birth in the delivery room
2. The resuscitation activities and events measured using the artificial intelligence-based judgement of the visual light video recording from the resuscitation table and manually labeled videos in retrospect as ground truth at the time of resuscitation

Secondary outcome measures
1. Compliance with resuscitation guidelines measured by comparing the manually labeled timelines and the AI-produced timelines with resuscitation guidelines in retrospect towards the end of the project when the AI models are working and the manual labeling is terminated

2. Successful resuscitation activity patterns measured using machine learning on the series of timelines compared with medical records on heart rate and the condition of the newborn at the end of the resuscitation in retrospect towards the end of the project
3. Number of consents, generated study IDs and collected videos of different types collected as a function of time measured using a digital patient consent handling and automated video data collection system to facilitate secure and accountable data collection throughout the data collection period

Overall study start date
01/09/2020

Completion date
31/08/2025

Eligibility

Key inclusion criteria
1. All women giving birth at the hospital
2. All newborns requiring resuscitation

Participant type(s)
Patient

Age group
Mixed

Sex
Both

Target number of participants
The expected sample size for newborns receiving resuscitation is approximately 500. The expected sample size of women giving births is > 500.

Key exclusion criteria
1. Non-consent from the mother
2. HCPs refraining from participation within 48 hours of the event
3. Birth in the labour room without cameras installed and no newborn resuscitation necessary

Date of first enrolment
15/11/2021

Date of final enrolment
31/08/2025

Locations

Countries of recruitment
Norway

Study participating centre
Stavanger University Hospital
Gerd-Ragna Bloch Thorsens gate 8
Stavanger
Norway
4019

Study participating centre
University of Stavanger
Kjell Arholms gate 41
Stavanger
Norway
4021

Study participating centre
Laerdal Medical
Tanke Svilands gate 30
Stavanger
Norway
4002

Study participating centre
BitYoga
Professor Olav Hanssens vei 7A
Stavanger
Norway
4021

Sponsor information

Organisation
University of Stavanger

Sponsor details
Kjell Arholms gate 41
Stavanger
Norway
4021
+47 51831000
post@uis.no

Sponsor type
University/education

Website
http://www.uis.no/frontpage/

ROR
https://ror.org/02qte9q33

Organisation
Stavanger University Hospital

Sponsor details
Gerd-Ragna Bloch Thorsens gate 8
Stavanger
Norway
4019
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post@sus.no

Sponsor type
Hospital/treatment centre

Website
http://www.helse-stavanger.no/en/Sider/default.aspx

ROR
https://ror.org/04zn72g03

Funder(s)

Funder type
Government

Funder Name
Norges Forskningsråd

Alternative Name(s)
Forskningsrådet, Norwegian Research Council, Research Council of Norway

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Norway

Funder Name
Helse Vest

Alternative Name(s)
Western Norway Regional Health Authority, WNRHA, Helse Vest Regionalt Helseføretak, Helse Vest RHF

Funding Body Type
Government organisation

Funding Body Subtype
Local government

Location
Norway

Funder Name
Fondation Idella

Alternative Name(s)
Foundation Idella

Funding Body Type
Private sector organisation

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

Location
Denmark

Funder Name
Universitetet i Stavanger

Alternative Name(s)
University of Stavanger, UiS, NOR

Funding Body Type
Private sector organisation

Funding Body Subtype

Universities (academic only)

Location
Norway

Results and Publications

Publication and dissemination plan
Planned publications in high-impact peer-reviewed technical and medical journals and at conferences

Intention to publish date
31/10/2025

Individual participant data (IPD) sharing plan
The dataset generated during the current study is not expected to be made available due to sensitivity of data and privacy concerns.

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		08/03/2023	09/03/2023	Yes	No