

# NewbornTime – Improved newborn care based on video and artificial intelligence

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| <b>Submission date</b><br>16/02/2023   | <b>Recruitment status</b><br>Recruiting               | <input type="checkbox"/> Prospectively registered<br><input checked="" type="checkbox"/> Protocol            |
| <b>Registration date</b><br>22/02/2023 | <b>Overall study status</b><br>Ongoing                | <input type="checkbox"/> Statistical analysis plan<br><input type="checkbox"/> Results                       |
| <b>Last Edited</b><br>09/03/2023       | <b>Condition category</b><br>Pregnancy and Childbirth | <input type="checkbox"/> Individual participant data<br><input type="checkbox"/> 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)

Prof Siren Rettedal, siren.irene.rettedal@sus.no (Norway)

### **Study website**

<https://www.uis.no/newborntime>

## **Contact information**

### **Type(s)**

Principal Investigator

### **Contact name**

Prof Kjersti Engan

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### **Type(s)**

Scientific

### **Contact name**

Prof Siren Rettedal

### **ORCID ID**

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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

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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? |
|----------------------------------|---------|--------------|------------|----------------|-----------------|
| <a href="#">Protocol article</a> |         | 08/03/2023   | 09/03/2023 | Yes            | No              |