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Measuring discomfort in extremely premature babies in Dutch neonatal care

Submission date
09/01/2026

Recruitment status
Recruiting

Registration date
06/02/2026

Overall study status
Ongoing

Last Edited
06/02/2026

Condition category
Neonatal Diseases

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

Plain English summary of protocol
Background and study aims
Extremely premature infants are exposed to many potentially stressful and uncomfortable procedures during daily care in neonatal intensive care units (NICUs). Accurate assessment of discomfort is important to provide optimal care. This multicenter study evaluates how well the COMFORTneo scale measures discomfort in infants born before 26 weeks of gestation in Dutch NICUs.

Who can participate?
Infants born at less than 26 weeks gestation, admitted to participating NICUs in the Netherlands

What does the study involve?
Discomfort is assessed three times daily during the first five days after birth using the COMFORTneo scale as part of routine care. Additional physiological measures, including near-infrared spectroscopy (NIRS) and skin conductance activity (SCA), are collected in a subset of infants. Data are analysed to evaluate the scale's performance across NICUs.

Possible benefits and risks of participating:
The study does not involve any interventions beyond routine care, so there are no additional risks. The findings may improve future assessment and management of discomfort in extremely preterm infants.

Where is the study run from?
University Medical Center Groningen (UMCG) and all participating NICUs in the Netherlands

When is the study starting and how long is it expected to run for?
May 2025 to January 2027

Who is funding the study?
University Medical Center Groningen (UMCG) (Netherlands)

Who is the main contact?
Mr Hendrik Koning, e.koning@umcg.nl

Contact information

Type(s)
Public, Scientific, Principal investigator

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Additional identifiers

Study information

Scientific Title
Assessing the discriminatory power of the COMFORTneo scale in extremely preterm infants

Acronym
XPREM

Study objectives
This prospective multicenter observational longitudinal cohort study evaluates the discriminatory power of the COMFORTneo scale in extremely preterm infants (<26 weeks gestation) admitted to neonatal intensive care units in the Netherlands. Discomfort is assessed three times daily for five consecutive days after birth as part of standard care. Additional physiological measures (near-infrared spectroscopy and skin conductance activity) are analyzed in a subset of infants. Item Response Theory and multilevel analyses are used to evaluate scale performance and variability between NICUs.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 18/02/2025, Central Ethics Review Board (Centraal Toetsingscommissie, CTc), UMCG – non-WMO studies (Hanzeplein 1, Groningen, 9700 RB, Netherlands; +31 (0)6-55257600/67925; nwmoloket@umcg.nl), ref: 21109

Primary study design
Observational

Secondary study design
Longitudinal study

Study type(s)

Health condition(s) or problem(s) studied
Discomfort, pain and stress assessment in extremely preterm infants

Interventions
This is a prospective multicenter observational longitudinal study. No interventions are assigned by the researchers. Discomfort and stress are assessed as part of standard neonatal intensive care using validated observational and physiological measures. COMFORTneo scores are recorded three times daily for five consecutive days after birth. Stress exposure is quantified using the Neonatal Infant Stressor Scale (NISS). Physiological parameters, including near-infrared spectroscopy (NIRS) and skin conductance activity (SCA), are collected in a subset of infants. Data are analyzed using multilevel and Item Response Theory analyses.

Intervention Type
Not Specified

Primary outcome(s)
1. Discomfort level measured using COMFORTneo scale score, NIRS at three times daily during the first 5 days after birth

Key secondary outcome(s))

Completion date
31/01/2027

Eligibility

Key inclusion criteria
1. Infants born at <26 weeks gestational age
2. Admitted to a neonatal intensive care unit (NICU)
3. Parental informed consent obtained

Healthy volunteers allowed
No

Age group
Neonate

Lower age limit
0 days

Upper age limit
5 days

Sex
All

Total final enrolment
0

Key exclusion criteria
1. Continuous sedative medication
2. Infants for whom parental informed consent is not obtained

Date of first enrolment
01/05/2025

Date of final enrolment
31/12/2026

Locations

Countries of recruitment
Netherlands

Sponsor information

Organisation
University Medical Center Groningen

ROR
https://ror.org/03cv38k47

Funder(s)

Funder type

Funder Name
Universitair Medisch Centrum Groningen

Alternative Name(s)
University Medical Center Groningen, UMCG

Funding Body Type
Government organisation

Funding Body Subtype
Local government

Location
Netherlands

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated and/or analysed during the current study will be stored in a non-publicly available repository (REDCap, UMCG) and will be made available upon reasonable request to the Principal Investigator (E. Koning, e.koning@umcg.nl), in accordance with parental consent and GDPR regulations.

Type of data: COMFORTneo scores, Neonatal Infant Stressor Scale (NISS) scores, NIRS measurements, and relevant demographic and clinical variables.
When data will be available: After completion of the study and publication of results (expected 2027).
Access criteria: Researchers with a justified scientific question, approved by the Principal Investigator, and adhering to GDPR and UMCG FAIR policies.
Consent: Parental consent obtained for use and sharing of data.
Anonymisation: All data will be pseudonymized; no direct identifiers will be shared.
Ethical/legal restrictions: Data will be shared for research purposes only; no commercial use is allowed without prior agreement.

IPD sharing plan summary

Available on request, Stored in non-publicly available repository