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Comparison between the effects of a 12-hour light-dark cycle and continuous 24-hour hospital lighting in preterm infants under 36 weeks of gestation

Submission date
27/07/2026

Recruitment status
No longer recruiting

Registration date
30/07/2026

Overall study status
Completed

Last Edited
31/07/2026

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
Premature babies often spend time in a neonatal intensive care unit (NICU), where the lights may stay on all day and night. Constant light can disrupt the body's natural day-night rhythm, which may affect growth and recovery. This study aims to find out whether exposing premature babies to a regular 12-hour light and 12-hour dark cycle leads to better health outcomes than continuous 24-hour lighting. Researchers will compare measures such as length of hospital stay, need for breathing support and feeding progress.

Who can participate?
Babies can take part if they:
-Were born between 26 weeks and 36 weeks of pregnancy
-Are admitted to the Neonatal Intensive Care Unit at Hospital General Regional 72 of the Instituto Mexicano del Seguro Social (IMSS) in Mexico
-Have consent provided by their parents or legal guardians
Babies with severe congenital abnormalities, trisomies or major structural malformations cannot take part.

What does the study involve?
Participants are assigned to one of two groups.
In the first group, babies are exposed to a 12-hour light-dark cycle. During the day (07:00 to 19:00), light levels are kept between 150 and 280 lux. During the night (19:00 to 07:00), cribs and incubators are covered to reduce light levels to less than 20 lux.
In the second group, babies receive standard care with continuous lighting at 150 to 280 lux throughout the day and night.

Researchers record information about each baby's hospital stay, feeding progress, need for mechanical ventilation, oxygen use, weight, length and head circumference until discharge from hospital.

What are the possible benefits and risks of participating?
Babies exposed to the 12-hour light-dark cycle may benefit from improved recovery. In this study, babies in the light-dark cycle group had shorter hospital stays, needed mechanical ventilation for fewer days and started enteral feeding earlier than babies exposed to continuous lighting.

The risks are expected to be low because the intervention involves changing lighting conditions rather than using medicines or invasive procedures. However, as with any study, there may be unforeseen risks.

Where is the study run from?
The study is being carried out in the Neonatal Intensive Care Unit of Hospital General Regional 72, Instituto Mexicano del Seguro Social (IMSS), in Tlalnepantla, State of Mexico, Mexico.

When is the study starting and how long is it expected to run for?
The first participant was enrolled on 23 July 2026. Recruitment ended on 24 July 2026. The study is expected to be completed on 30 July 2026.

Who is funding the study?
The study is funded by the Instituto Politécnico Nacional (National Polytechnic Institute, Mexico).

Who is the main contact?
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Study information

Scientific Title

Effects of a 12-hour light-dark cycle compared to continuous 24-hour lighting on clinical outcomes and length of hospital stay in preterm infants under 36 weeks of gestation in the Neonatal Intensive Care Unit of the Hospital General Regional 72, Instituto Mexicano del Seguro Social

Study objectives
To compare the effects of exposure to a 12-hour light-dark circadian cycle versus continuous 24-hour lighting on clinical outcomes and length of hospital stay in preterm infants under 36 weeks of gestation.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 01/01/2026, CONBIOETICA (Calzada Arenal No. 134, esquina con Xochimaltzin, Colonia Arenal Tepepan, Alcaldía Tlalpan, Ciudad de México, 14610, Mexico; +55 5487 2760; conbioetica.contacto@salud.gob.mx), ref: conbioetica.contacto@salud.gob.mx

Primary study design
Interventional

Allocation
Randomized controlled trial

Masking
Open (masking not used)

Control
Active

Assignment
Single

Purpose
Health services research

Study type(s)

Health condition(s) or problem(s) studied
Circadian rhythm disruption in preterm infants in the NICU

Interventions
A controlled clinical trial was conducted in the Neonatal Intensive Care Unit (NICU) of Hospital General Regional 72 of the Instituto Mexicano del Seguro Social (IMSS), located in Tlalnepantla, State of Mexico. The study population consisted of a final analyzed sample of 40 preterm infants with a gestational age between 26 and 36 weeks at birth.

The population was divided into two groups: The experimental group (n = 19) was exposed to a controlled 12-hour light-dark circadian cycle, characterized by a daytime phase (from 07:00 to 19: 00 h) with illuminance levels between 150 and 280 lux, and a night time phase (from 19:00 to 07:

00 h) during which cribs and incubators were covered with opaque blankets to reduce lighting to less than 20 lux. On the other hand, the control group (n = 21) received conventional management with continuous 24-hour lighting, maintaining a sustained illuminance range between 150 and 280 lux. Following the intervention, total length of hospital stay, cycle duration, days of mechanical ventilation requirement, days of supplemental oxygen use, as well as time to initiation of enteral feeding and time to reach full enteral feeding were evaluated and compared between both groups.

For intervention assignment, participants were randomized using block randomization (10 blocks of 4 participants each). The randomization list was generated via Sealed Envelope (Sealed Envelope Ltd. 2024).

Intervention Type
Other

Primary outcome(s)
1. Length of hospital stay measured using days at between baseline/initial time point: second day of life/admission to the Neonatal Intensive Care Unit (NICU) and final time point: hospital discharge

2. Time to iInitiation of enteral feeding measured using days at between baseline/initial time point: second day of life/admission to the Neonatal Intensive Care Unit (NICU) and final time point: hospital discharge

3. Duration of mechanical ventilation measured using days at between baseline/initial time point: second day of life/admission to the Neonatal Intensive Care Unit (NICU) and final time point: hospital discharge

Key secondary outcome(s)
1. Weight measured using grams (g) at between baseline/initial time point: second day of life /admission to the Neonatal Intensive Care Unit (NICU) and final time point: hospital discharge

2. Length measured using centimeters (cm) at between baseline/initial time point: second day of life/admission to the Neonatal Intensive Care Unit (NICU) and final time point: hospital discharge

3. Head circumference measured using centimeters (cm) at between baseline/initial time point: second day of life/admission to the Neonatal Intensive Care Unit (NICU) and final time point: hospital discharge

4. Time to full enteral feeding measured using days at between baseline/initial time point: second day of life/admission to the Neonatal Intensive Care Unit (NICU) and final time point: hospital discharge

5. Duration of supplemental oxygen requirement measured using days at between baseline /initial time point: second day of life/admission to the Neonatal Intensive Care Unit (NICU) and final time point: hospital discharge

Completion date
30/07/2026

Eligibility

Key inclusion criteria
1. Preterm infants between 26 and 36 weeks of gestational age
2. Patients admitted to the Neonatal Intensive Care Unit (NICU) of the Hospital General Regional 72,Instituto Mexicano del Seguro Social (IMSS)
3. Informed consent signed by parents or legal guardians

Healthy volunteers allowed
No

Age group
Child

Lower age limit
26 Weeks

Upper age limit
36 Weeks

Sex
All

Total final enrolment
40

Key exclusion criteria
1. Lethal congenital malformations
2. Trisomies
3. Structural defects or malformations

Date of first enrolment
23/07/2026

Date of final enrolment
24/07/2026

Locations

Countries of recruitment
Mexico

Sponsor information

Organisation
Instituto Politécnico Nacional

ROR
https://ror.org/059sp8j34

Funder(s)

Funder type

Funder Name
Instituto Politécnico Nacional

Alternative Name(s)
National Polytechnic Institute, Instituto Politécnico Nacional | Mexican Institution, Instituto Politécnico Nacional (Mexico) (IPN), , IPN

Funding Body Type
Government organisation

Funding Body Subtype
Universities (academic only)

Location
Mexico

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Spanish		30/07/2026	No	Yes