Evaluation of the safety, effectiveness and natural care approach of the Jauni phototherapy romper.

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Ethical review	Approved WMO
Status	Recruiting
Health condition type	Hepatic and hepatobiliary disorders
Study type	Interventional

Summary

ID

NL-OMON56682

Source
ToetsingOnline

Brief title
Jauni Care Study 1

Condition

- Hepatic and hepatobiliary disorders

Synonym
icterus, Jaundice

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Bilihome,Bilihome en een Holland Health TKI subsidie

Intervention

Keyword: Bilirubin, Jaundice, Phototherapy

Outcome measures

Primary outcome

The main endpoint is safe and effective phototherapy treatment using Jauni.

Safe treatment is defined as no adverse events that necessitate the switch to a conventional phototherapy device, as indicated by the independent expert.

Effective treatment is defined as ability to discontinue phototherapy within 48 hours after initiation (i.e. total serum bilirubin level >50 µmol/L below phototherapy threshold according to the Dutch National hyperbilirubinaemia guideline).

Secondary outcome

Satisfaction of parents (surveyed in semi-structured interview)

Satisfaction of healthcare professionals with Jauni (assessed in individual interview immediately after newborn phototherapy treatment).

Reduction of bilirubin levels in µmol/L/hr during phototherapy with Jauni.

Safety indicators (e.g., hypo/hyperthermia, skin redness/rash).

(Serious) adverse events

Total duration of phototherapy in hours

Total duration of hospitalization

Percentage of neonates requiring phototherapy with a conventional device

Percentage of neonates requiring admission to the neonatology department for phototherapy

Percentage of neonates requiring exchange transfusion, according to the Dutch

hyperbilirubinemia guideline.

Study description

Background summary

The majority of newborn babies experience a degree of jaundice during the first week of life, due to temporary elevation of bilirubin levels. If bilirubin levels are too high, this may cause neurological damage, leading to potentially severe life-long handicaps. Phototherapy, the first-line treatment for neonatal jaundice, is currently the commonest reason for hospital (re)admission in the neonatal period. However, increasing evidence indicates that phototherapy treatment can also safely and effectively be provided at home. This may overcome high costs associated with hospital admission and help address increasing challenges regarding hospital capacity, while promoting parent-child bonding. The current phototherapy devices that may be used in the home setting - a mattress and a sleeping bag - have significant drawbacks hampering their widespread implementation. These devices require connection to mains electricity for example, resulting in physical barrier for parents to provide natural care to their neonate. Bilihome has developed Jauni: the first wearable phototherapy device, integrated into a romper.

Study objective

We will assess safety (potential adverse events related to phototherapy using Jauni, e.g. skin injuries, hyperthermia, or hypothermia) and effectiveness (e.g. rate of lowering of bilirubin levels, duration of phototherapy need) of phototherapy using Jauni.
Additionally, we will explore the experience of parents and healthcare providers regarding Jauni and care for the neonate during phototherapy so as to facilitate future transition to home care for neonatal jaundice.

Study design

A prospective single-arm pilot intervention study.

Intervention

Phototherapy using Jauni.

Study burden and risks

In this study, we will assess the safety and effectivity of phototherapy using Jauni. This study can only be conducted in neonates, since they are the only group suffering from neonatal hyperbilirubinaemia and necessitating phototherapy treatment.
Jauni is based on the same technique of blue LED light as commercially available, widely used conventional phototherapy devices. The risk assessment of the Jauni device did not show any residual risks of an unacceptable level after risk control measures were in place. Bilihome has provided a declaration of safety of the Jauni.
An independent expert will assess safety and effectiveness of Jauni after each participant that completed phototherapy before the next participant is included. If the independent expert considers Jauni to be unsafe or ineffective, the next participant will not be included until the case has been assessed thoroughly and the independent expert considers Jauni safe and likely effective for the next participant.
Additionally, phototherapy using Jauni may have advantages. Jauni is developed to promote the natural care approach during phototherapy. Consequently, kangaroo care, breastfeeding, and parent-child bonding may be eased in comparison to conventional phototherapy devices.
In conclusion, we consider the risks of participating in the study low, with potential advantages: Jauni is based on an existing, proven technique, a safety declaration is provided by the manufacturer, each neonate is evaluated by an independent expert, and natural care can potentially be provided more easily.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Newborns

Inclusion criteria

- Born at or after a gestational age of 38 weeks.
If after participation of six low-risk neonates, the independent expert has not identified any safety issues and effectiveness seems plausible, the eligibility criteria will be extended to also include neonates born between 36 and 38 weeks of gestation.
- Total bilirubin level above phototherapy treatment threshold, according to the Dutch guideline or phototherapy indicated by a paediatrician.{[Dutch Paediatric Society] Nederlandse Vereniging voor Kindergeneeskunde, 2023 #328}
- Older than 24 hours of postnatal age.
- No risk factors* applicable for the subject, according to Dutch guideline.{[Dutch Paediatric Society] Nederlandse Vereniging voor Kindergeneeskunde, 2023 #328}
*Risk factors - blood group antagonisms - other haemolytic disorders - asphyxia (AS 5 min < 5 or umbilical cord pH < 7.0 - ill, drowsy, suspected infection/sepsis - (albumin < 30 g/Ll, (if determined)

Exclusion criteria

- Conjugated hyperbilirubinaemia (indirect/conjugated bilirubin levels >10 µmol/L or >20% of total bilirubin level, if known).
- Bilirubin level not higher than: ((phototherapy threshold + exchange transfusion threshold) / 2). According to the Dutch guideline. Unless the attending paediatrician decides otherwise based on clinical criteria.{[Dutch Paediatric Society] Nederlandse Vereniging voor Kindergeneeskunde, 2023 #328}>XX µmol/L above phototherapy treatment threshold.
- Neonates having any contraindication for the use of Jauni:
- Subjects with congenital erythropoietic porphyria or other photosensitising disorders.
- Subjects under photosensitive medication.
- Subjects with skin conditions, categorised as unsuitable for an on-skin treatment by a healthcare professional.

- Subjects with fever.
- The healthcare provider considers the neonate not suitable for phototherapy using Jauni (with reasons noted).
- Parents do not provide written informed consent.

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	17-05-2024
Enrollment:	12
Type:	Actual

Medical products/devices used

Generic name:	Jauni Romper
Registration:	No

Ethics review

Approved WMO Date:	05-04-2024
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	17-05-2024
Application type:	Amendment

Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Not approved Date:	11-02-2025
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL85903.000.23