Implementation of a Transcutaneous Bilirubinometer among Newborns: A Randomized Controlled Trial

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To optimize the quality and cost-effectiveness of care for jaundiced neonates in the Isala Klinieken.

Ethical review	Approved WMO
Status	Pending
Health condition type	Neonatal and perinatal conditions
Study type	Interventional

Summary

ID

NL-OMON37522

Source
ToetsingOnline

Brief title
Transcutaneous Bilirubinometer

Condition

- Neonatal and perinatal conditions

Synonym
hyperbilirubinemia, neonatal jaundice

Research involving
Human

Sponsors and support

Primary sponsor: Isala Klinieken
Source(s) of monetary or material Support: Isala vakgroep kindergeneeskunde;onderzoek in eigen tijd.

Intervention

Keyword: hyperbilirubinemia, neonatal jaundice, transcutaneous bilirubinometry, visual assessment of jaundice

Outcome measures

Primary outcome

Primairy outcome variable: the number of blood tests for bilirubin measurement

(Before the potential start of phototherapy).

Secondary outcome

Secondary outcome: Phototherapy duration in hours, Number of serum

bilirubin-values above the 'exchange transfusion limit', Highest measured serum

bilirubin-value, Cost-effectiveness (blood test, use bilirubinometer, costs

admittance), Number of patients having kernicterus.

Study description

Background summary

Neonatal jaundice, caused by hyperbilirubinemia, is frequently seen in healthy newborns. Severe hyperbilirubinemia can cause bilirubin encephalopathy (kernicterus). Assessment of the degree of jaundice is usually done visually,and if necessary serum bilirubin is investigated in a blood sample. The visual assessment is subjective and can alternatively be replaced by transcutaneous measurement.The transcutaneous bilirubinometer is a validated measurement-tool, which provides us with an estimated serum bilirubin-concentration. Little is known about the effect of the actual use of a bilirubinometer on the quality of care. Further evidence is needed to evaluate whether transcutaneous bilirubin measurements improve clinical outcome (use of blood tests, phototherapy and exchange transfusion), shorten length of stay and reduce costs.

Study objective

To optimize the quality and cost-effectiveness of care for jaundiced neonates

in the Isala Klinieken.

Study design

Randomised controlled trial

Intervention

One group receives transcutaneous measurements, the other group receives the standard of care: visual assessment
Transcutaneous bilirubinometer: JaundiceMeter-103®, Dräger

Study burden and risks

non-invasive intervention, duration: at most 5 seconds
no risks

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Children (2-11 years)

Inclusion criteria

All newborns at the pediatric- and maternity-ward with visible jaundice.
Gestational age of 32 weeks or more.
Older than 24 hours.
younger than 8 days.

Exclusion criteria

Neonatal jaundice within 24 hours or after 8 days
Hemolysis present based on maternal history (for example irregular erythrocyte antibodies)
Bilirubin encephalopathy
Newborns during/after phototherapy
Large congenital anomaly at forehead/sternum
Serum bilirubin-value is already known before admission to the pediatric ward;those newborns are to be admitted because the serum bilirubin-level has reached the phototherapy or exchange transfusion limit.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)

Primary purpose: Health services research

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-04-2013
Enrollment:	550
Type:	Anticipated

Medical products/devices used

Generic name:	transcutaneous bilirubinometer
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	25-02-2013
Application type:	First submission
Review commission:	METC Isala Klinieken (Zwolle)

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
ClinicalTrials.gov	NCT01622699
CCMO	NL40354.075.12