Objective assessment of illness severity of infants presented at the Emergency General Practitioner Post.

Published: 16-11-2023
Last updated: 02-12-2024

Primary Objective: to assess the feasibility of the use of BabyCheck combined with standard PO for infants < six months of age presented at the emergency GP post. Secondary Objective(s): 1. To assess the sensitivity and specificity of the…

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Viral infectious disorders
Study type	Observational non invasive

Summary

ID

NL-OMON56144

Source
ToetsingOnline

Brief title
Baby Sickness Evaluation (BeSurE)

Condition

- Viral infectious disorders
- Upper respiratory tract disorders (excl infections)

Synonym
level of illness, Systemic illness

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum
Source(s) of monetary or material Support: Medtronic

Intervention

Keyword: BabyCheck, Pulse oximetry, Screening, Young infant

Outcome measures

Primary outcome

Feasibility will be determined by calculating the percentage of eligible infants in whom a complete Babycheck score and PO data were retrieved. We consider the protocol feasible if this is done in 80% of all eligible infants..

Secondary outcome

Sensitivity and specificity of the combined BabyCheck-PO score: a referral to the pediatric department is assigned just if no treatment, diagnostic tools or follow up is performed in hospital, which could not have been performed at the GP post.

Acceptability of GPs will be assessed by asking three questions at the end of the web-based data collection form:

1) Was the combination of questions and pulse oximetry useful for assessing illness severity in this infant? [yes/no]

2) Did the outcome of the scores influence your decision for referral? [yes/no]

3) Do you have any comments for the researchers? [open field]

Acceptability of pediatricians/pediatric residents will be assessed by adding 3 questions in the electronic patient file at the BabyCheck field:

In the electronic patient file system, we will build three questions:

1) was the referral necessary or just [yes/no]

2) was the referral possibly previously missed or too much delayed [yes/no].

3) Was the combination of BabyCheck and PO useful in assessing illness severity

in this infant? [yes/no]

Study description

Background summary

Young infants visit general practitioners (GP) frequently with acute pathology, such as infections.1-4 Assessing severity of illness in this group is often challenging, since many symptoms, such as crying and vomiting, can occur both in mildly ill infants as well as in sicker infants.5-7 Deterioration of the clinical condition can occur more rapidly, allthough the likelihood of serious illness in this group is low,. 8 Therefore, early recognition of pathology in young babies is pivotal. The Netherlands Triage System (derived from the Manchester Triage System) is a reliable tool for both children and adults to decide if a patient should be seen by the GP. 9 However, after presentation at the GP, a scoring system to assess illness severity in babies with a decision aid for referral to hospital, is currently lacking. Both unnecessary and delayed referral are undesirable. Delayed referral of infants who are actually severely ill may lead to delay in effective treatment and impede a favorable outcome. Evaluation at the emergency department (ED) is time consuming for parents, patients and health care providers. Also, the paediatric ED is relatively cost-inefficient for low acuity concerns.10 In Great Britain, a scoring system was developed and validated as a clinical checklist to quantify the severity of illness in young infants up to six months of age. This scoring system, called BabyCheck, contains nineteen signs and symptoms, grading the severity of illness. The BabyCheck is validated in multiple low illness prevalent settings.11-14 Also, it was considered as practical and manageable by parents and GPs.15,16 A randomised controlled trial states that distribution of BabyCheck booklets to an unselected group of mothers did not have effect on the use of GP services for their infants. However, the authors also state that BabyCheck might prove more valuable with a more thorough implementation strategy.17 Low oxygen saturation (SpO2) can be an early sign of infection, respiratory or circulatory pathology in infants.18,19 Since it is difficult to adequately judge oxygen saturation solely by skin colour and obtaining heart rate (HR) by auscultation is often inaccurate, it is preferable to objectify these parameters via pulse oximetry (PO). These parameters could be useful to decide whether referral is necessary, but also to decide which method of transport to the ED is justifiable. However, pulse oximetry (PO) is rarely performed by GPs in young infants, although it is widely used in older children and adults. Most GP practices do not have an appropriate PO device or sensor for young babies. (inventory survey among GPs). With this study we aim to assess the feasibility of combining BabyCheck with standard PO for infants <

six months of age presented at the emergency GP post in order to aid the decision for referral to the hospital.

Study objective

Primary Objective: to assess the feasibility of the use of BabyCheck combined with standard PO for infants < six months of age presented at the emergency GP post. Secondary Objective(s): 1. To assess the sensitivity and specificity of the combination of BabyCheck and PO for just referral (treatment or diagnostic in hospital, which would not have been possible in primary care setting) 2. To assess GPs* acceptability of using BabyCheck and PO as a triage system for sickness evaluation in young babies

Study design

This is a feasibility trial for a single center prospective trial performed at the emergency GP post in Leiderdorp as well as at the pediatric department of the Alrijne Hospital in Leiderdorp. The proposed triage system of BabyCheck combined with PO will be assessed during a period of six months.

Study burden and risks

This research consist of a standard oxygen saturation and heart rate measurement via a pulseoximetry and the calculation of the BabyCheck score based on standard anamnesis and physical examination.
The BabyCheck is proven to be an effective tool to quantify the level of sickness in babies. Pulseoximetry is a non-invasive test and measuring oxygen saturation is considered standard of care in highrisk infants at birth therefore widely used.

Even if the values from the pulseoximetry and BabyCheck don't give an indication to refer to the pediatrician, the general practitioner is always justified to consult a pediatrician. The responsibility to refer remains with the general practitioner. It is therefore not expected that the research causes harm to the infant.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Babies and toddlers (28 days-23 months)
Newborns

Inclusion criteria

Infants up to six months of age, presenting with systemic illness at the emergency GP post of Leiderdorp.

Exclusion criteria

- Infants up to six months of age, presenting with traumata or that are in a resuscitation setting. - Infants with referral to other hospitals than the Alrijne hospital. The location for referral is coded and available from the anonymized database of the emergency GP post. - Infant < 1 month of age presenting with fever (body temperature > 38.0 *C), with or without unknown origin, since these infants should always be referred according to the national guidelines for GPs. [NHG richtlijn kinderen met koorts]. - Infants < 3 months of age presenting with fever of uknown origin (temperature > 38.0 *C), since these infants should always be referred according to the national guidelines for GPs.[NHG richtlijn kinderen met koorts].

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-03-2024
Enrollment:	360
Type:	Actual

Medical products/devices used

Generic name:	Pulse oximeter Nellcor PM10N
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	16-11-2023
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO

Date:	17-06-2024
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

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	NCT05954975
CCMO	NL84259.058.23