Telemedicine in pediatric respiratory distress: a pilot study

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1. Are telemedicine and FTF-evaluation similar?2. Are TM-evaluation from a general practitioners office and FTF-evaluation similar? 3. How do parents/patients value the TM evaluation?4. How do general practitioners and paediatricians value the TM...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Respiratory tract infections
Study type	Observational non invasive

Summary

ID

NL-OMON48278

Source
ToetsingOnline

Brief title
Telemedicine in general practice setting

Condition

- Respiratory tract infections

Synonym
Respiratory distress, shortness of breath

Research involving
Human

Sponsors and support

Primary sponsor: Rijnstate Ziekenhuis
Source(s) of monetary or material Support: Rijnstate

Intervention

Keyword: General practitioner, Pediatrics, Respiratory distress, Telemedicine

Outcome measures

Primary outcome

Patients are categorized in one of three categories through TM-evaluation

Group 1: *Patient can safely go home"

Group 2: *Patient will need to be admitted*

Group 3: *In doubt between group 1 and group 2, emergency room consultation

required"

FTF evaluation:

Group 1: *Patient can safely go home"

Group 2: *Patient will need to be admitted*

Secondary outcome

Respiratory Observation Checklist

Amount of delay due to the telemedicine assessment

Patient evaluation

Doctors evaluation

Study description

Background summary

Children with respiratory symptoms are frequently seen in the emergency rooms across the Netherlands. In Rijnstate Hospital around 1000 emergency room

consultations by pediatric patients with respiratory symptoms are performed. There is a distinct pattern throughout the year with more patients in the first and last quarter, with a peakincidence in January and February (RIVM, 2013). Children with respiratory symptoms usually spend between 2-4 hours in our emergency rooms. Around 50% of these patients are admitted, the others are discharged home. These numbers are most likely similar in other hospitals in the Netherlands.

The patients who are discharged have a significant strain by having to travel to the hospital while being ill, waiting in our emergency room before being discharged home. This time- and travelstrain might well be reduced by using telemedicine.

It is hypothesized that telemedicine applications and software allow for a reliable examination of the child in respiratory distress. By examining the patient through telemedicine the pediatrician can make a quatlity judgement whether the patient needs to be seen in the emergency room or can be safely discharged home with advice on when to reconnect with their general practitioner. Also, the patients who are referred to our emergencyroom have been examined before and will be able to go through our clinical examination in a shorter period of time. We expect that patients and their parents will need to get used to the idea of telemedicine, but will be pleased in the end because of less travel and waiting time.

Study objective

1. Are telemedicine and FTF-evaluation similar?
2. Are TM-evaluation from a general practitioners office and FTF-evaluation similar?
3. How do parents/patients value the TM evaluation?
4. How do general practitioners and paediatricians value the TM evaluation?

Study design

Part 1:
Determining the safety and applicability of the software.
Children with respiratory distress who are already referred to our emergency room will receive an extra physical examination by telemedicine and by a face-to-face examination by the same doctor while they are waiting in the emergency room. If the examination in real life and the telemedicine examination are congruent part 2 of the study will commence.

Part 2:
Determining wether telemedicine works over long-distance connection with general practitioner offices.
Children with respiratory symptoms whom the general practitioner was going to

refer to our emergency room will first be examined using telemedicine after which they will be seen in real life on our emergency room to study whether both physical examinations coincide.

Study burden and risks

Burden of the study consists of 1-2 extra physical examinations of which one will be via telemedicine.
Additionally patients/parents will receive a questionnaire for evaluating the telemedicine.

Participation may result in a delay of customary examination and therefore treatment of approximately 15-30 minutes.
The risks associated with this delay are judged as minimal because the patient is accompanied by a physician throughout the delay. Should the patients condition deteriorate the general practitioner will continue to have the opportunity to request for an ambulance.

Should the paediatrician examining the patient judge the respiratory distress to be significant, the paediatrician can advice for an ambulance to be called to transfer the patient to the hospital and thereby shortening the transportation significantly.

A child with respiratory symptoms can suddenly develop to respiratory insufficiency. However this is particularly the case in children younger than 2 months whom are not included in the study. Older children can potentially deteriorate quickly however it is easier to determine their rate of respiratory distress and it is expected that a delay of 15-30 minutes will not lead to significant risk.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Children (2-11 years)

Inclusion criteria

Pediatric patients with respiratory symptoms whom are referred by a general practitioner to be evaluated by a pediatrician

Exclusion criteria

- Infants younger than 2 months of age
- 19 years and older
- Ex-premature with post-conceptional age <48 weeks
- Congenital heart disease
- Down Syndrome
- Immune deficiency
- Pre-existent pulmonary disorder (Broncho-pulmonary dysplasia, Cystic Fibrosis)
- Pre-existent neurological disorders
- Apnea's
- Patients with respiratory distress with dehydration symptoms
- Patients who have already been treated with salbutamol inhalers of nebulizer
- Emergency patient with respiratory insufficiency
- Technical problems which cause a delay longer than 10 minutes before a video-connection is made

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Health services research

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	29-01-2020
Enrollment:	40
Type:	Actual

Medical products/devices used

Generic name:	Telemedicine
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	11-11-2019
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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	NL68739.091.19