

## BEISPIELSTUDIE

### **Emergency ultrasound-assisted examination of skin and soft tissue infections in the paediatric emergency department.**

#### **KATEGORISIERUNG**

##### **Gattung**

Forschungsprojekt mit lebenden Personen

##### **Art**

##### **Unterart**

Klinischer Versuch mit Medizinprodukten (nach KlinV-Mep)

#### **BACKGROUND**

This study evaluated the test characteristics of clinical examinations of paediatric patients, supplemented with bedside emergency ultrasound, and compared them to clinical examination alone, to identify skin and soft tissue infections that require drainage. The ultrasound device bears a CE mark, but is not used as intended. Since the bedside emergency ultrasound was added to clinical practice and the investigation of the clinical performance of adding bedside ultrasound was the goal of the study, the study qualifies as a clinical trial (and not as an observational study according to HRO chapter 2). - The study is conducted by an academic sponsor, who does not intend to use the data generated in the study to establish or demonstrate the conformity of the device for the new purpose investigated in the study.

#### **METHODS**

This was a prospective study of clinical examinations, supplemented with bedside emergency ultrasound, as a diagnostic test to evaluate patients 2 months to 19 years old. These patients were evaluated for skin and soft tissue infections in a paediatric emergency department. Each patient was clinically examined by the responsible physician (standard) and by an independent radiologist, who performed a bedside emergency ultrasound (result not communicated to the responsible physician). The reference standard that determined if a lesion required drainage was defined as "pus expressed at the time of the emergency department visit or within 2 days by follow-up assessment". The primary outcome was the degree of agreement between clinical exam alone, and clinical exam supplemented with ultrasound, on the number of lesions that required drainage within 2 weeks after clinical examination. No other study-related procedures were performed except for the ultrasound.

#### **CATEGORISER-FRAGEN**

##### **Fällt das Forschungsprojekt in den Geltungsbereich des Humanforschungsgesetzes?**

Ja

##### **BECAUSE**

This project was based on a study protocol that defines the exact procedures to be used. It included a relatively large number of persons and was not based on individual cases ("method-driven search for generalizable knowledge", defined as research by HRA). Children ("persons") aged 2 months to 19 years, who suffered from skin and soft tissue infections ("research concerning human diseases") were clinically examined and were given bedside emergency ultrasound.

**Handelt es sich bei dem Forschungsprojekt um ein Projekt mit lebenden Personen?**

Ja

**BECAUSE**

Children ("persons") aged 2 months to 19 years, who suffered from skin and soft tissue infections, were included in this research project.

**Handelt es sich bei dem Forschungsprojekt um einen klinischen Versuch im Sinne der KlinV oder der KlinV-Mep?**

Ja

**BECAUSE**

The performance of an ultrasound device ("medical device") was systematically tested in children ("persons") aged 2 months to 19 years, who suffered from skin and soft tissue lesions. The goal was to examine how consistent two examination techniques were in diagnosing lesions that require drainage.

**Wird in der Studie ein Medizinprodukt (In-vitro-Diagnostika ausgenommen) oder ein anderes Produkt nach Artikel 1 der Medizinprodukteverordnung (MepV) (Stand am 26. Mai 2022) untersucht?**

Ja

**BECAUSE**

The performance of an ultrasound device ("medical device") was systematically tested in children ("persons").