Trial Description

Title

"Intelligent" sensor-equipped shoe insole for patients with diabetic neuropathy for prophylaxis of foot ulcers (ulcer)

Trial Acronym

ISS

URL of the trial

[---]*

Brief Summary in Lay Language

The trial will examine planned 300 patients over a 2-year period if a shoe insole equipped with sensors can prevent foot injuries in diabetics with nerve damage. Nerves in the feet have the task to give us information about touch, pressure and temperatures. If they are injured, falls, (unnoticed) injuries, permanently open wounds and joint misalignments due to incorrect loading will follow. With the development of a smart insole, the goal is to replace the lost information. Sensors take over the task of damaged nerves. It will be investigated whether the feedback of pressure and temperature changes can prevent the occurrence of foot ulcers.
This new care method deviates from standard therapy and has not been previously approved. The routine care for patients with nerve damage includes protective footwear with ready-made or custom-made soles, which tailor orthopedic shoemakers according to the medical advice. The insole is designed according to the shape of the foot and consists of materials that distribute the applied compressive forces as evenly as possible. However, punctual loads can not be completely compensated in this way. Pressure stresses that lead to dreaded circulatory disorders and ulcerations are not always prevented. That's why the intelligent shoe insole was developed. In contrast to conventional insoles, it is equipped with several wafer-thin pressure and temperature sensors as well as a data memory chip. The sensors are incorporated into the insole so that they themselves do not exert any pressure and are not felt. During the measurement, they record the pressure and temperature values of the feet and send them to a mobile phone (smartphone). There, the result of the measurement is displayed. The measurement results are transferred from the smartphone to the study center. Should the temperature values of the feet indicate an incipient ulcer, the smartphone sends a message to the study center.

Brief Summary in Scientific Language

In diabetic patients, foot complications arise from the interaction of macro- and microangiopathic vascular changes and nerve damage (neuropathy). Both the poorer perception of pathological changes on the feet in case of nerve damage (lack of pressure, temperature, pain perception), as well as the higher probability of emergence due to regional circulatory disorders cause a vicious circle with a tendency to foot ulcers, chronic inflammation caused by tissue defects and concomitant infections with massive patient disabilities in terms of mobility,

quality of life, and life expectancy.
The purpose of this clinical trial is to investigate the hypothesis that a foot ulcer recorded twice daily using the smart sensor-equipped insole, which does not yet have CE certification, can be used to reduce the risk of ulcer formation.
Patients should wear the smart insoles at morning and night in open slippers for at least 5 minutes for measurement purposes.
The purpose of this clinical trial is to determine whether morning and evening temperature monitoring can be used to detect early onset of foot ulcers early and thus provide better prevention of ulcer over the standard routine of recommended daily care to prevent the development of ulcers.

Do you plan to share individual participant data with other researchers?

No

Description IPD sharing plan

[---]*

Organizational Data

- DRKS-ID: **DRKS00013798**
- Date of Registration in DRKS: **2018/01/18**
- Date of Registration in Partner Registry or other Primary Registry: **[---]***
- Investigator Sponsored/Initiated Trial (IST/IIT): **yes**
- Ethics Approval/Approval of the Ethics Committee: **Approved**
- (leading) Ethics Committee Nr.: **176/17 , Ethikkommission der Medizinischen Fakultät der Otto-von-Guericke-Universität Magdeburg**

Secondary IDs

- Universal Trial Number (UTN): **U1111-1207-7482**
- EUDAMED-No.
(for studies acc. to Medical Devices act): **CIV-17-10-021964**

Health condition or Problem studied

- ICD10: **E10.74 - [generalization E10.7: Type 1 diabetes mellitus; With multiple complications]**
- ICD10: **E11.74 - [generalization E11.7: Type 2 diabetes mellitus; With multiple complications]**

Interventions/Observational Groups

- Arm 1: **Experimental arm = 150 patients: Equipment of the intervention groups with "intelligent" insoles and smartphone app, 2x daily measurement (at least 5 min) of the foot temperatures, instruction in the recommended daily care measures to avoid the development of ulcers;**
  After the measurement, feedback is given to the patient as to whether the measurement was successful. If differences in temperature should be detectable study participants with the help of the mobile phone take a photo of the foot and if possible of the sole of the foot (with the help of others) on both sides . A repetition of the temperature measurement follows and the data is transmitted pseudonymized to the database. FU visits 6, 12, 18 and 24 months after confinement
- Arm 2: **Comparison group = 150 patients: briefing on the recommended daily care measures to avoid the development of ulcers;**

  This includes a regular self-inspection, pedicure, as well as the adherence to medical check-ups, on own responsibility by the patient, and serves the early detection of ulcerations. The daily measures of foot care for prevention include:
  • Daily cleaning of the feet with lukewarm water
  • rub with moisturizer
  • Proper blunt nail care
  • elimination of calluses
  • Supply with suitable footwear
  FU visits 6, 12, 18 and 24 months after confinement

Characteristics

- Study Type: **Interventional**
- Study Type Non-Interventional: **[---]***
- Allocation: **Randomized controlled trial**
- Blinding: **[---]***
- Who is blinded: **[---]***
- Control: **Active control (effective treament of control group)**
- Purpose: **Prevention**
- Assignment: **Parallel**
- Phase: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **No**

Primary Outcome

Acquisition of foot ulcerations at any time during a 24-month intervention with a "smart" shoe insole compared to a non-intervention group without information through a smart shoe insole. The number and time to reach the endpoint are the primary targets. If such an endpoint is reached, the severity level is classified according to the Wagner-Armstrong classification. For the study participants, the exam concludes on reaching the primary endpoint or after the 24 months have elapsed.

Secondary Outcome

**a) safety information related to diabetes,
the equipment (insole)**
• frequency of occurrence of AEs
• Frequency of occurrence of SAEs
b) Precursors of the primary endpoint
• redness in the foot area
• Infections in the foot area
• Wounds in the foot area
**c) an effect of the occurrence of a preliminary stage or
the primary endpoint on quality of life**
d) recording the adherence to the daily two-time temperature measurement based on data acquisition of the app,
e) recording the frequency of the alert in the intervention group based on the data collection of the app,
f) Detection of slow temperature drops as an indication of circulatory disorders (PAD)
g) recording the adherence to the photo documentation

Countries of recruitment

- DE **Germany**

Locations of Recruitment

- University Medical Center **Universitätsklinik für Nieren- und Hochdruckkrankheiten, Diabetologie und Endokrinologie, Magdeburg**

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2018/01/30**
- Target Sample Size: **300**
- Monocenter/Multicenter trial: **Monocenter trial**
- National/International: **National**

Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **18 Years**
- Maximum Age: **85 Years**

Additional Inclusion Criteria

- Diabetes mellitus type 1 or type 2
- ages between 18 and 85 years
- Sensomotoric peripheral diabetic polyneuropathy (sensation of vibration by means of a graduated tuning fork according to Rydel / Seiffer </ = 4/8)
- Missing neuropathic ulcers in the foot area in the anamnesis (risk group 2) or healed neuropathic ulcers in the foot area in the anamnesis (risk group 3)
- Good general condition
- capacity to consent
- written consent after clarification
- Dealing with mobile phone and app after instruction possible

Exclusion criteria

- Existing foot ulcers at the beginning of the clinical trial
- Macroangiopathy of the lower extremities (ABI <0.5)
- Risk group 0-1 according to the classification system for shoe care and risk assessment in diabetic foot syndrome [9]
- heart failure St. III / IV according to NYHA
- Active tumor disease
- Physical deformities (amputations, foot, leg, spinal deformities affecting the gait)
- Visual impairment, so that the use of an app using a tablet can not be performed
- Myocardial infarction before ≤ 12 weeks
- pregnancy
- Any other reason that, in the opinion of the investigator, precludes participation.

Addresses

■ **Primary Sponsor**

Otto-von-Giericke University Magdeburg
Medical Faculty
Mr. Prof. Dr. med. Hermann-Josef ROTHKÖTTER
Leipziger Str. 44
39120 Magdeburg
Germany

Telephone: **+ 49391 67 15750**
Fax: **+ 49 391 67 15749**
E-mail: **hermann-josef.rothkoetter at med.ovgu.de**
URL: **[---]***

■ **Contact for Scientific Queries**

Universitätsklinik für Nieren- und Hochdruckkankheiten
Mr. Prof. Dr. med. Peter R. Mertens
Leipziger Str. 44
39120 Magdeburg
Germany

Telephone: **+49-391-67-13236**
Fax: **[---]***
E-mail: **peter.mertens at med.ovgu.de**
URL: **http://www.knep.ovgu.de/**

■ **Contact for Public Queries**

Universitätsklinik für Nieren- und Hochdruckkrankheiten, Diabetologie und Endokrinologie
Ms. Dr. med. Isabell Walter
Leipziger Str. 44
39120 Magdeburg
Germany

Telephone: **+49-301-67-21745**
Fax: **[---]***
E-mail: **isabell.walter at med.ovgu.de**
URL: **http://www.knep.ovgu.de/**

- **Collaborator, Other Address**

  Thorsis Technologies GmbH
  Mr. Dipl. Ing. Thorsten Szczepanski
  Oststr. 18
  39114 Magdeburg
  Germany

  Telephone: **+49-391-544-563-1001**
  Fax: **[---]***
  E-mail: **kontakt at thorsis.com**
  URL: **[---]***

- **Collaborator, Other Address**

  Medixmind GmbH
  Mr. Fred Samland
  Oststr. 1
  39114 Magdeburg
  Germany

  Telephone: **+49-391-557606-21**
  Fax: **[---]***
  E-mail: **[---]***
  URL: **[---]***

Sources of Monetary or Material Support

- **Public funding institutions financed by tax money/Government funding body (German Research Foundation (DFG), Federal Ministry of Education and Research (BMBF), etc.)**

  Bundesministerium für Wirtschaft und Energie (BMWi)Referat EA3
  EFRE
  Scharnhorststr. 34-37
  10115 Berlin
  Germany

  Telephone: **+49-30-18615-6226**
  Fax: **[---]***
  E-mail: **buero-ea3 at bmwi.bund.de**
  URL: **http://www.bmwi.de/Redaktion/DE/Dossier/europaeische-wirtschaftspolitik.html**

Status

- Recruitment Status: **Recruiting complete, follow-up complete**
- Reason, if "Recruitment stopped after recruiting started" or "Recruiting withdrawn before recruting started": **[---]***

- Reason, if Reason for Recruiting Stop "Other": **[---]***
- Study Closing (LPLV): **2021/03/19**
- Number of Participants in Germany after Recruiting complete: **286**
- Total Number of Participants (all Sites worldwide) after Recruiting complete: **286**

Trial Publications, Results and other documents

- trial protocol (mandatory for transfer to Studybox) **Publikation Study Protocol**

** This entry means the parameter is not applicable or has not been set.*

**** This entry means that data is not displayed due to insufficient data privacy clearing.*