Trial Description

Title

Efficient healthcare for children with cancer using telemedicine in Schleswig-Holstein

Trial Acronym

KULT-SH

URL of the trial

https://www.uksh.de/paediatrie-kiel/kultsh.html

Brief Summary in Lay Language

Children with cancer receiving chemotherapy have secondary bone marrow failure and severe infections can occur. In order to recognize such complications in time, frequent, sometimes even daily, doctor-patient contacts in a pediatric oncology center are necessary. About one third of all appointments serve to capture vital sings and to obtain an overall clinical impression. At the other appointments, chemotherapy or transfusions as well as procedures such as bone marrow punctures are necessary.
In the KULT-SH project, a part of the on-site visits will be replaced by telemedicine. Technical sensors enable the measurement of vital parameters at home. Via the project's own KULT-SH app and a tablet PC, audio-video conferences are held with doctors of the pediatric oncology of the University Medical Center Schleswig-Holstein in Kiel. All children and adolescents with cancer from the age of 1 year who are still in intensive therapy for at least 6 months with an anticipated number of at least 2x weekly doctor-patient contacts can participate. Sufficient language skills are required and internet access must be available at home.
The aim of the study is to show an equivalence of telemedical support compared to on-site visits regarding safety aspects. Furthermore, the acceptance of telemedicine by patients and families as well as their quality of life and a possible reduction in treatment costs are evaluated.

Brief Summary in Scientific Language

Children with cancer have an increased risk of life-threatening infections due to chemotherapy-induced immunodeficiency. In order to recognize these complications in time, high-frequency clinical visits in pediatric oncology departments are necessary. About one third of all appointments serve to capture vital parameters and identify subtle clinical signs of a beginning infection, without the need for further diagnostic or therapeutic interventions.
In the KULT-SH project, these appointments will be replaced by telemedicine. Therefore, audio-video conferences and the project’s own KULT-SH app will be used. Technical devices at home record vital parameters.
KULT-SH is a monocentric randomized crossover study at the Department of Pediatric Oncology in Kiel. First patients will be included from January 2021.
The aim of the study is to show an equivalence of telemedical support in respect to severe complications compared to on-site visits. Further outcomes are the

evaluation of patient satisfaction and quality of life as well as a possible reduction of treatment costs. Therefore, quantitative, qualitative and health economic analyses are carried out.

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

No

Description IPD sharing plan

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Organizational Data

- DRKS-ID: **DRKS00021042**
- Date of Registration in DRKS: **2020/04/03**
- 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.: **D 431/20 , Ethikkommission der Christian-Albrechts-Universität zu Kiel**

Secondary IDs

Health condition or Problem studied

- ICD10: **C00-C97 - Malignant neoplasms**

Interventions/Observational Groups

- Arm 1: **Immediate starter: during the first 3 months, all on-site visits without the need of diagnotic or therapeutic interventions (laboratories, punctions, chemotherapy, transfusions e.g.) are replaced by telemedical visits. All other appointments remain unchanged. This period is followed by on-site visits without telemedical support also for 3 months. If desired, an on-demand telemedical period is possible. This corresponds to the process of Phase 1.**
- Arm 2: **Waiting Group: during the first 3 months, we carry out on-site visits without telemedical support. This period is followed by a 3-month phase during which on-site visits without the need of diagnostic or therapeutic interventions (laboratories, punctions, chemotherapy, transfusions e.g.) are replaced by telemedical visits. All the other appointments remain unchanged. If desired, an on-demand telemedical period is possible. This corresponds to the process of Phase 2 (3.-6. months).**

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: **Health care system**
- Assignment: **Crossover**
- Phase: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **N/A**

Primary Outcome

Statistical evidence of equivalence of telemedical support regard to severe complications compared to on-site visits. Therefore, the cumulative score of severe complications (NCI-CTCAE) is measured after 3 and 6 months.

Secondary Outcome

Proof that the “time-to-antibiotic” is not prolonged by the telemedical intervention compared to on-site visits

AND

Proof that patients and their families experience improvements in their health care and health status using telemedicine. "PREMS" and "PROMS" are recorded.

Countries of recruitment

- DE **Germany**

Locations of Recruitment

- University Medical Center **Klinik für Kinder- und Jugendmedizin I, Pädiatrische Hämatologie und Onkologie, Kiel**

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2021/07/27**
- Target Sample Size: **60**
- Monocenter/Multicenter trial: **Monocenter trial**
- National/International: **National**

Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **1 Years**
- Maximum Age: **25 Years**

Additional Inclusion Criteria

Newly diagnosed malignant disease or malignant disease under Treatment OR condition after allogeneic hematopoietic stem cell Transplantation under drug-immunosuppressive therapy.
AND age ≥ 1 year to 25 years.
AND therapy Duration from inclusion ≥ 6 months.
AND anticipated high-frequency contact phases (≥ 2 doctor-patient contacts per week during therapy).
AND internet access at home.

Exclusion criteria

Inclusion criteria not available AND/OR poor language skills which do not allow for a video-/audio conference

Addresses

■ **Primary Sponsor**

Dekanat der Medizinischen Fakultät, Christian-Albrechts-Universität zu Kiel
Christian-Albrechts-Platz 4
24118 Kiel
Germany

Telephone: **[---]***
Fax: **[---]***
E-mail: **[---]***
URL: **https://www.medizin.uni-kiel.de/de**

■ **Contact for Scientific Queries**

Christian-Albrechts-Universität zu Kiel, Universitätsklinikum Schleswig-Holstein, Klinik für Kinder- und Jugendmedizin I, Pädiatrische Hämatologie und Onkologie,
Mr. PD Dr. Denis Martin Schewe
Arnold-Heller-Straße 3, Haus C
24105 Kiel
Germany

Telephone: **0431 500 20140**
Fax: **0431 500 20204**
E-mail: **denis.schewe at uksh.de**
URL: **https://www.uksh.de**

■ **Contact for Public Queries**

Christian-Albrechts-Universität zu Kiel, Universitätsklinikum Schleswig-Holstein, Klinik für Kinder- und Jugendmedizin I, Pädiatrische Hämatologie und Onkologie,
Mr. PD Dr. Denis Martin Schewe
Arnold-Heller-Straße 3, Haus C
24105 Kiel
Germany

Telephone: **0431 500 20140**
Fax: **0431 500 20204**
E-mail: **denis.schewe at uksh.de**
URL: **https://www.uksh.de**

■ **Collaborator, Other Address**

Institut für Sozialmedizin und Epidemiologie, Universität zu Lübeck,
Mr. Dr. Dr. Fabian-Simon Frielitz
Ratzeburger Allee 160 (Haus 50)
23538 Lübeck
Germany

Telephone: **0451 500 51212**
Fax: **0451 500 51204**
E-mail: **Fabian.Frielitz at uksh.de**
URL: **https://www.zbv.uni-luebeck.de/zbv.html**

■ **Collaborator, Other Address**

Institut für Medizinische Informatik und Statistik der Christian-Albrechts-Universität Kiel,
Mr. Prof. Dr. Björn Bergh
Brunswiker Str. 10
24105 Kiel
Germany

Telephone: **0431 500 30706**
Fax: **0431 500 30704**
E-mail: **Bjoern.Bergh at uksh.de**
URL: **https://www.uni-kiel.de/medinfo/institut/index.html**

■ **Collaborator, Other Address**

Techniker Krankenkasse, Landesvertretung Schleswig-Holstein
Ms. Johanna Kampmann
Hopfenstr. 2c, I. OG
24114 Kiel
Germany

Telephone: **043198158519**
Fax: **043198158555**
E-mail: **johanna.kampmann at tk.de**
URL: **[---]***

- **Collaborator, Other Address**

  DAK-Gesundheit, Landesvertretung Schleswig-Holstein
  Mr. Tom Pukowski
  Hopfenstr. 60
  24103 Kiel
  Germany

  Telephone: **04313890231119**
  Fax: **04033470276353**
  E-mail: **tom.pukowski at dak.de**
  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.)**

  Innovationsausschuss beim Gemeinsamen Bundesausschuss
  Gutenbergstraße 13, Postfach 12 06 06
  10596 Berlin
  Germany

  Telephone: **[---]***
  Fax: **[---]***
  E-mail: **info at if.g-ba.de**
  URL: **https://innovationsfonds.g-ba.de/**

Status

- Recruitment Status: **Recruiting ongoing**
- Reason, if "Recruitment stopped after recruiting started" or "Recruiting withdrawn before recruting started": **[---]***
- Reason, if Reason for Recruiting Stop "Other": **[---]***
- Study Closing (LPLV): **[---]***
- Number of Participants in Germany after Recruiting complete: **[---]***
- Total Number of Participants (all Sites worldwide) after Recruiting complete: **[---]***

Trial Publications, Results and other documents

- Approval of ethics comm. (mandatory for transfer to Studybox) **Ethikvotum**
- trial protocol (mandatory for transfer to Studybox) **Studienprotokoll**

** 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.*