PLEASE NOTE: This trial has been registered retrospectively.

**Trial Description**

**Title**
APVEL - Evaluation of the effectiveness of specialized outpatient palliative care (SAPV) in North Rhine

**Trial Acronym**
APVEL

**URL of the trial**
https://www.apvel.de/

**Brief Summary in Lay Language**
The project APVEL is investigating the effectiveness of specialized outpatient palliative care. It assesses the extent of symptom relief and improvement of quality of life that can be achieved by a palliative care team as part of assisting a patient with an advanced disease at home.

**Brief Summary in Scientific Language**

The GBA Guideline on Specialized Outpatient Palliative Care (SAPV) will be evaluated in three regions in North Rhine, describing the effectiveness of the SAPV as reflected in routine data, providers' views and direct patient-oriented outcomes to provide recommendations for an update.

The concept includes the following modules:

1.1) Retrospective analysis of pseudonymised secondary data of insurants from the AOK Rheinland/ Hamburg (2014-2016). Here, patient characteristics, routes of care, duration of SAPV are described and differences in care for AAPV (general outpatient palliative care) patients and standard care in the last year of life are analyzed.

1.2) Quantitatively, the attitude and prescription practice of general practitioners and oncologists with regard to SAPV (vs. AAPV or standard care) is examined.

2) Prospectively, the effectiveness of the SAPV compared to the AAPV and standard provision in 3 urban vs. 3 rural regions around Aachen, Bonn and Cologne is analyzed.

3) From the data developed, recommendations for the further development of SAPV are formulated.

**Organizational Data**

- **DRKS-ID:** DRKS00014748
- **Date of Registration in DRKS:** 2018/06/06
- **Date of Registration in Partner Registry or other Primary Registry:** [---]*
Secondary IDs

Health condition or Problem studied

- Free text: patients with advanced incurable diseases

Interventions/Observational Groups

- Arm 1: SAPV patients in urban provision areas are questioned quantitatively at T0 by means of IPOS / Facit-Pal-14 and qualitatively with a semi-structured interview guide at their homes; at T1 (after 5 days) only the quantitative part is collected again by telephone contact; as well on T2 and T3 after each 5 days.

- Arm 2: SAPV patients in rural provision areas are questioned quantitatively at T0 by means of IPOS / Facit-Pal-14 and qualitatively with a semi-structured interview guide at their homes; at T1 (after 5 days) only the quantitative part is collected again by telephone contact; as well on T2 and T3 after each 5 days.

- Arm 3: AAPV patients in urban provision areas are questioned quantitatively at T0 by means of IPOS / Facit-Pal-14 and qualitatively with a semi-structured interview guide at their homes; at T1 (after 5 days) only the quantitative part is collected again by telephone contact; as well on T2 and T3 after each 5 days.

- Arm 4: AAPV patients in rural provision areas are questioned quantitatively at T0 by means of IPOS / Facit-Pal-14 and qualitatively with a semi-structured interview guide at their homes; at T1 (after 5 days) only the quantitative part is collected again by telephone contact; as well on T2 and T3 after each 5 days.

- Arm 5: general practitioners and oncologists in North Rhine are questioned by means of a questionnaire on the reasons for assignment to the different forms of palliative care provision, the cooperation with the palliative care stakeholders and the organizational conditions.

- Arm 6: Analysis of pseudonymised routine data of insured persons of the AOK Rheinland / Hamburg residing in the region North Rhine. It collects master data including insurance periods, as well as data on outpatient medical care, hospital treatment and rehabilitation, ordinance data, medication and aids, selected other services (hospice stays) as well as data from the statutory long-term care insurance. All insured persons (18 years and older) who died in the
years 2014 to 2016 are evaluated. For the analysis of prevalence of palliative care use, a population is also made up of all insured persons (18 years and older) who have received at least one documented palliative benefit from 2014 to 2016. For the analysis of prevalence of palliative care use, a population is also made up of all insured persons (18 years and older) who have received at least one documented palliative benefit from 2014 to 2016. In addition to AAPV and SAPV, palliative services of outpatient standard care as well as in-patient services are taken into account. Based on this data, statements are to be made on the following areas:

- Share of patients using services
- Time of first order and duration of supply
- Death
- Differences in patients in SAPV and AAPV (regarding demography, morbidity, performance and other factors)

It also analyzes which patient characteristics influence prescription, as well as differences between SAPV and AAPV patients with respect to chemotherapy in the last three months of life in cancer patients, placement of a PEG probe in dementia patients and implantation of an implantable defibrillator in heart failure patients.

Characteristics

- Study Type: **Non-interventional**
- Study Type Non-Interventional: **Observational study**
- Allocation: **Non-randomized controlled trial**
- Blinding: [---]*
- Who is blinded: [---]*
- Control: **Other**
- Purpose: **Health care system**
- Assignment: **Other**
- Phase: N/A
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): N/A

Primary Outcome

Outpatient trail: IPOS global sum score

Secondary Outcome

[---]*

Countries of recruitment

- DE Germany
Locations of Recruitment

- University Medical Center Klinik für Palliativmedizin, Aachen
- University Medical Center Zentrum für Palliativmedizin, Köln
- University Medical Center Klinik für Palliativmedizin, Bonn
- University Medical Center IMVR, Köln
- University Medical Center pmv Forschungsgruppe, Köln

Recruitment

- Planned/Actual: Actual
- (Anticipated or Actual) Date of First Enrollment: 2017/12/29
- Target Sample Size: 256
- Monocenter/Multicenter trial: Multicenter trial
- National/International: National

Inclusion Criteria

- Gender: Both, male and female
- Minimum Age: 18 Years
- Maximum Age: no maximum age

Additional Inclusion Criteria

Minimum age 18 years, patient with an incurable advanced tumor or non-tumor disease (e.g., neurological diseases or heart, lung, liver, kidney disease), ECOG 0-3,
Prior informed consent and written consent of the patient or health care proxy / legal guardian,
Patient receiving outpatient palliative care provision

Exclusion criteria

Inability to give informed and written consent,
Patient without a representative or legal guardian who can give consent for study participation,
relation of dependency with the examiner

Addresses

- Primary Sponsor

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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.)
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Status

- Recruitment Status: Recruiting complete, follow-up complete
- Study Closing (LPLV): 2019/04/01

Trial Publications, Results and other documents

* 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.