Trial Description

Title

RADprecise - Personalized radiotherapy: incorporating cellular response to irradiation in personalized treatment planning to minimize radiation toxicity

Trial Acronym

RADprecise

URL of the trial

[---]*

Brief Summary in Lay Language

The RADprecise collaborative project aims to personalize radiotherapy treatment for cancer patients. We plan to improve the prediction of the risk for side effects after radiotherapy using multiple biomarkers in addition to clinical and personal factors. Information from the prediction models shall be incorporated into radiotherapy treatment planning systems.

Brief Summary in Scientific Language

**The aim of this collaborative translational project is to personalize radiotherapy (RT) treatment for cancer patients by incorporating information from improved predictive models for RT-induced
toxicity based on data from multiple biomarkers of individual radiosensitivity into treatment planning systems.**

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

Yes

Description IPD sharing plan

If patients gave their consent, pseudonymized data can be shared with external Researchers after the end of the project. This requires a scientifically Sound concept form to be submitted to the coordinator and, after approval, a data transfer agreement to be signed.

Organizational Data

- DRKS-ID: **DRKS00020290**
- Date of Registration in DRKS: **2020/01/03**
- Date of Registration in Partner Registry or other Primary Registry: **[---]***
- Investigator Sponsored/Initiated Trial (IST/IIT): **yes**

DRKS-ID: **DRKS00020290**
Date of Registration in DRKS: **2020/01/03**
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.: **S-583/2019 , Ethik-Kommission I der Medizinischen Fakultät Heidelberg**

Secondary IDs

Health condition or Problem studied

- ICD10: **C50 - Malignant neoplasm of breast**
- ICD10: **C61 - Malignant neoplasm of prostate**

Interventions/Observational Groups

- Arm 1: **- Breast and prostate cancer patients who received radiotherapy are followed up annually for radiotherapy related side effects and complete a questionnaire on quality of life/patient reported outcomes.**
  - Biomarkerassays

Characteristics

- Study Type: **Non-interventional**
- Study Type Non-Interventional: **Other**
- Allocation: **Single arm study**
- Blinding: **[---]***
- Who is blinded: **[---]***
- Control: **Uncontrolled/Single arm**
- Purpose: **Other**
- Assignment: **Single (group)**
- Phase: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **N/A**

Primary Outcome

- Breast: Breast toxicities after a minimum of 3 years after radiotherapy

- Prostate gastro-intestinal (GI): Gastrointestinal toxicity after a minimum of 3 years after radiotherapy

- Prostate genito-urinary (GU): Urinary toxicity after a minimum of 3 years after radiotherapy

Secondary Outcome

- Other toxicity endpoints including but not limited to: cosmesis, vascular changes, pain (breast); erectile dysfunction (prostate)
- Patient reported outcomes
- Quality of life, fatigue

Countries of recruitment

- DE **Germany**
- IT **Italy**
- ES **Spain**
- UK **United Kingdom**

Locations of Recruitment

- University Medical Center **Mannheim**
- Medical Center **Karlsruhe**
- Medical Center **Darmstadt**
- Doctor's Practice **Speyer**
- Doctor's Practice **Freiburg im Breisgau**
- Medical Center **Mailand**
- Medical Center **Santiago de Compostela**
- Medical Center **Barcelona**
- University Medical Center **Leicester**

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2020/06/15**
- Target Sample Size: **1050**
-

Planned/Actual: **Actual**

(Anticipated or Actual) Date of First Enrollment: **2020/06/15**

Target Sample Size: **1050**

Monocenter/Multicenter trial: **Multicenter trial**

- National/International: **International**

Inclusion Criteria

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

Additional Inclusion Criteria

- Adult breast or prostate cancer patients who received radiotherapy and have participated in the REQUITE study in Germany, Italy, Spain, UK and who are alive at re-contact
- Willingness and ability to comply with at least one scheduled visit
- The capacity to understand the patient information sheet and the ability to provide written informed consent

Exclusion criteria

- Re-irradiation of the region of initial radiotherapy (including contralateral breast)
- Any breast surgery after initial RT, mastectomy patients (including contralateral breast)
- Mental disability or patient otherwise unable to give informed consent and/or complete patient questionnaires
- Known HIV infection, hepatitis B or hepatitis C not eligible for sample collection

Addresses

- **Primary Sponsor**

  Deutsches Krebsforschungszentrum (DKFZ) / German Cancer Research Center
  69120 Heidelberg
  Germany

  Telephone: **[---]***
  Fax: **[---]***
  E-mail: **[---]***
  URL: **[---]***

- **Contact for Scientific Queries**

  Deutsches Krebsforschungszentrum

Contact for Scientific Queries

Deutsches Krebsforschungszentrum
Ms. Prof. Jenny Chang-Claude
Im Neuenheimer Feld 581
69120 Heidelberg
Germany

Telephone: **0049-(0)6221-42-2200**
Fax: **[---]***
E-mail: **j.chang-claude at dkfz.de**
URL: **www.dkfz.de**

■ **Contact for Public Queries**

Deutsches Krebsforschungszentrum (DKFZ)
Ms. Prof. Jenny Chang-Claude
Im Neuenheimer Feld 581
69120 Heidelberg
Germany

Telephone: **0049-(0)6221-42-2200**
Fax: **[---]***
E-mail: **j.chang-claude at dkfz.de**
URL: **www.dkfz.de**

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 Bildung und Forschung
10115 Berlin
Germany

Telephone: **[---]***
Fax: **[---]***
E-mail: **[---]***
URL: **www.bmbf.de**

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

ANR - Agence Nationale de la Recherche
75012 Paris
France

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

ANR - Agence Nationale de la Recherche
75012 Paris
France

Telephone: **[---]***
Fax: **[---]***
E-mail: **[---]***
URL: **[---]***

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

FRRB - Fondazione Regionale per la Ricerca Biomedica - Regional Foundation for Biomedical Research
20124 Milan
Italy

Telephone: **[---]***
Fax: **[---]***
E-mail: **[---]***
URL: **[---]***

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

ISCIII - National Institute of Health Carlos III
28029 Madrid
Spain

Telephone: **[---]***
Fax: **[---]***
E-mail: **[---]***
URL: **[---]***

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

DS-CAT - Health Department – Generalitat de Catalunya
08028 Barcelona
Spain

Telephone: **[---]***
Fax: **[---]***
E-mail: **[---]***

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

DS-CAT - Health Department – Generalitat de Catalunya
08028 Barcelona
Spain

Telephone: **[---]***
Fax: **[---]***
E-mail: **[---]***
URL: **[---]***

Status

- Recruitment Status: **Recruiting ongoing**
- Study Closing (LPLV): **[---]***

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.*