

Trial Description

Title

German prospective register study for detecting the treatment of gynecological sarcomas in clinical routine

Trial Acronym

REGSA

URL of the trial

[---]*

Brief Summary in Lay Language

Sarcomas are rare tumors and even more rarely affect the gynecological organs such as the uterus and ovaries. In Germany about 200 to 300 women fall ill every year at a sarcoma of the uterus.

Although carcinosarcomas account for <5% of all uterine malignancies, they are associated with >15 % of uterine cancer-associated deaths. This aggressive behavior along with its unique histological appearance represents a diagnostic challenge.

But an effective targeted therapy requires in advance an accurate diagnosis of the tumor subgroups by immunohistochemical and molecular techniques.

It is always important to plan the detailed treatment as an overall concept which includes the operating procedures, the systematic analysis of the tumor tissue, but also the discussion of possible chemo- and hormonal therapy respectively radiation or targeted cancer therapies, which is adapted to individual risk. At this the therapy regimes differs substantially from different tumor types and individual situation.

The introduction of a gynecological sarcoma register is an important precondition for the improvement of the diagnostics and treatment of sarcomas and treatment of them. This register is the possibility to have more information on the incidence of individual sarcoma subtypes and their treatment to generate the standard of care.

Brief Summary in Scientific Language

Sarcomas are rare tumors and even more rarely affect the gynecological organs such as the uterus and ovaries. In Germany about 200 to 300 women fall ill every year at a sarcoma of the uterus.

Although carcinosarcomas account for <5% of all uterine malignancies, they are associated with >15 % of uterine cancer-associated deaths. This aggressive behavior along with its unique histological appearance represents a diagnostic challenge.

But an effective targeted therapy requires in advance an accurate diagnosis of the tumor subgroups by immunohistochemical and molecular techniques.

It is always important to plan the detailed treatment as an overall concept which includes the operating procedures, the systematic analysis of the tumor tissue, but also the discussion of possible chemo- and hormonal therapy respectively



radiation or targeted cancer therapies, which is adapted to individual risk. At this the therapy regimes differs substantially from different tumor types and individual situation. A survey among 374 gynaecologists could show that there is a great uncertainty concerning the standard therapy of uterine sarcomas.

The introduction of a gynecological sarcoma register is an important precondition for the improvement of the diagnostics and treatment of sarcomas and treatment of them. This register is the possibility to have more information on the incidence of individual sarcoma subtypes and their treatment to generate the standard of care.

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

[---]*

Description IPD sharing plan

[---]*

Organizational Data

- DRKS-ID: **DRKS00009240**
- Date of Registration in DRKS: **2015/08/18**
- 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.: **EA2/041/15 , Ethik-Kommission der Charité - Universitätsmedizin Berlin-**

Secondary IDs

Health condition or Problem studied

- Free text: **Leimyosarcom**
- Free text: **endometrial stromal sarcoma**
- Free text: **undifferentiated endometrial stroma sarcom**
- ICD10: **C49 - Malignant neoplasm of other connective and soft tissue**
- ICD10: **C54 - Malignant neoplasm of corpus uteri**

Interventions/Observational Groups



- Arm 1: **documentation of the current treatment of gynaecological sarcoma and their treatment success after 12 month regardless of type of therapy and line of therapy**

Characteristics

- Study Type: **Non-interventional**
- Study Type Non-Interventional: **Observational study**
- 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

- 1. Complete detection of gynecological sarcomas in Germany**
- 2. Registration and safeguarding of diagnostic and therapeutic standards at different subtypes**

Secondary Outcome

- 1. Basis for innovative new therapeutic concepts**

Countries of recruitment

- DE **Germany**
- AT **Austria**
- CH **Switzerland**

Locations of Recruitment

- University Medical Center **Charité Universitätsmedizin Berlin, Campus Virchow-Klinikum, Klinik für Frauenheilkunde, Berlin**
- Medical Center **Kreisklinik Altötting, Gynäkologische geburtshilfliche Abteilung, Altötting**
- Medical Center **Klinikum Fürth, Frauenklinik, Fürth**



- Medical Center **Klinikum Neumarkt, Neumarkt**
- Medical Center **Leopoldina-Krankenhaus der Stadt Schweinfurt GmbH, Schweinfurt**
- Medical Center **Klinikum Bayreuth GmbH, Klinik für Frauenheilkunde und Geburtshilfe, Bayreuth**
- Medical Center **Klinikum Passau, Frauenklinik, Passau**
- Medical Center **Donau-Ries-Klinik Donauwörth, Abteilung Gynäkologie und Geburtshilfe, Donauwörth**
- Medical Center **Klinikum Kempten-Oberallgäu gGmbH, Klinik für Frauenheilkunde und Geburtshilfe, Kempten**
- University Medical Center **Frauenklinik, Tübingen**
- Medical Center **Klinik für Frauenheilkunde und Geburtshilfe, Starnberg**
- Medical Center **Sana Klinikum Lichtenberg, Gynäkologisches Krebszentrum, Berlin**
- Doctor's Practice **Mühlhausen**
- Doctor's Practice **Erfurt**
- Medical Center **Klinikum Esslingen Frauenheilkunde und Geburtshilfe, Esslingen am Neckar**
- Medical Center **Schwarzwald-Baar Klinikum, Frauenheilkunde und Geburtshilfe, Villingen-Schwenningen**
- Medical Center **Ev. Diakonissenkrankenhaus, Frauenklinik, Karlsruhe**
- Medical Center **Rems Murr Kliniken Winnenden, Gynäkologie und Geburtshilfe, Winnenden**
- University Medical Center **Universitätsklinikum Freiburg, Frauenheilkunde und Geburtsmedizin, Freiburg im Breisgau**
- Medical Center **Kliniken Südostbayern AG Frauenklinik, Traunstein**
- Medical Center **Missionsärztliche Klinik, Gemeinnützige Gesellschaft mbH, Abteilung Gynäkologie und Geburtshilfe, Würzburg**
- Medical Center **Klinikum Straubing, Straubing**
- Medical Center **Klinikum Nürnberg, Klinik für Frauenheilkunde, Nürnberg**
- Medical Center **Vivantes, Netzwerk für Gesundheit GmbH, Klinikum Neukölln, Klinik für Gynäkologie, Berlin**
- Medical Center **Brustzentrum Park-Klinik Weißensee, Abteilung Gynäkologie, Berlin**
- Medical Center **Klinikum Dahme-Spreewald GmbH, Achenbach-Krankenhaus, Abt. Gynäkologie und Geburtshilfe, Königs Wusterhausen**
- Medical Center **Ruppiner Kliniken GmbH, Klinik für Gynäkologie und Geburtshilfe, Neuruppin**
- Medical Center **Agaplesion Diakonieklinikum Hamburg, Zert. Gyn. Tumorzentrum, Hamburg**
- University Medical Center **Universitätsklinikum Hamburg-Eppendorf, Hamburg**



- Medical Center **Hochwaldkrankenhaus, Gynäkologische Ambulanz, Bad Nauheim**
- Medical Center **St. Vinzenz-Krankenhaus Hanau gGmbH, Geb. gyn. Abteilung, Hanau**
- Medical Center **Agaplesion Markus Krankenhaus, Klinik für Gynäkologie und Geburtshilfe, Frankfurt a.M.**
- Medical Center **Hochtaunus-Kliniken gGmbH, Bad Homburg**
- Medical Center **Krankenhaus-Neu-Mariahilf, Göttingen**
- Medical Center **Klinikum Wolfsburg, Wolfsburg**
- Medical Center **Klinikum Osnabrück GmbH, Klinik für Frauenheilkunde und Geburtshilfe, Osnabrück**
- Medical Center **Niels-Stensen-Kliniken, Marienhospital Osnabrück, Osnabrück**
- Medical Center **Klinikum Emden, Hans-Susemihl-Krankenhaus gGmbH, Emden**
- University Medical Center **Universitätsklinikum Greifswald, Klinik und Poliklinik für Frauenheilkunde und Geburtshilfe, Greifswald**
- Medical Center **Augusta-Kranken-Anstalt Bochum, Bochum**
- Medical Center **Klinikum Gütersloh gGmbH, Gütersloh**
- Medical Center **St. Elisabeth Gruppe GmbH, Marien Hospital Witten, Geb.-Gyn.-Abteilung, Witten**
- University Medical Center **Universitätsklinikum Düsseldorf, Düsseldorf**
- Medical Center **Katharinen Hospital Unna, Gynäkologie/Geburtshilfe/Senologie, Unna**
- Medical Center **Kliniken Essen Mitte, Klinik für Gynäkologie und Gyn. Onkologie, Essen**
- University Medical Center **Uniklinik Köln, Klinik für Frauenheilkunde und Geburtsmedizin, Köln**
- Medical Center **Dritter Orden, München**
- Medical Center **Knappschaftsklinikum Saar GmbH, Krankenhaus Püttlingen, Püttlingen**
- Medical Center **<style fontName='DejaVu Sans' isBold='true'>Elblandkliniken Stiftung & Co. KG, Elblandklinikum Riesa, Riesa</style>**
- University Medical Center **Universitätsklinikum Carl Gustav Carus Dresden, an der Technischen Universität Dresden, Gynäkologisches Krebszentrum und Regionales Brustzentrum Dresden, Dresden**
- Medical Center **Klinikum St. Georg gGmbH, Gynäkologische Onkologie/ Frauenklinik, Leipzig**
- Medical Center **DRK gemeinnütziges Krankenhaus GmbH Sachsen, DRK Krankenhaus Chemnitz-Rabenstein, Chemnitz**
- Medical Center **Städtisches Klinikum Dessau, Dessau**
- University Medical Center **Universitätsklinikum Halle (Saale), Universitätsklinik und Poliklinik für Gynäkologie, Halle Saale**
- Medical Center **Regio Klinikum Pinneberg, Gynäkologie und Geburtshilfe, Pinneberg**



- Medical Center **Städtisches Krankenhaus Kiel GmbH, Kiel**
- University Medical Center **Universitätsklinikum Jena, Klinik für Frauenheilkunde und Geburtshilfe, Jena**
- Medical Center **Martin-Luther-Krankenhaus, Berlin**
- Medical Center **Diakonissen-Stiftungs-Krankenhaus Speyer, Speyer**
- Medical Center **Diakonie-Klinikum Schwäbisch Hall gGmbH, Frauenklinik mit Brustzentrum und Gyn. Krebszentrum, Schwäbisch Hall**
- Medical Center **Klinikverbund Südwest, Klinikum Sindelfingen-Böblingen, Kliniken Böblingen, Frauenklinik, Böblingen**
- Medical Center **Klinikum Chemnitz gGmbH, Chemnitz**
- Medical Center **Diakoniekrankenhaus Henriettenstiftung Hannover, Brustzentrum, Hannover**
- Medical Center **Ev. Krankenhaus Oberhausen, Oberhausen**
- University Medical Center **Universitätsklinikum Essen, Essen**
- Medical Center **St. Marien-Krankenhaus Siegen gGmbH, Siegen**
- Medical Center **Klinikum Dortmund gGmbH, Dortmund**
- University Medical Center **Universitätsklinik der Johannes-Gutenberg-Universität Mainz, Mainz**
- University Medical Center **Universitätsklinikum des Saarlandes, Homburg / Saar**
- University Medical Center **Universitätsklinikum Schleswig-Holstein, Kiel**
- Medical Center **Thüringen-Kliniken "Georgius Agricola" GmbH, Saalfeld**
- Medical Center **DRK - Krankenhaus Sömmerda, Sömmerda**
- Medical Center **Klinikum Konstanz, Konstanz**
- University Medical Center **Klinikum Mannheim, Mannheim**
- Medical Center **Ortenau Klinikum, Offenburg**
- University Medical Center **Universitätsfrauenklinik Ulm, Ulm**
- University Medical Center **Klinikum St. Marien, Amberg**
- Medical Center **Klinikum Aschaffenburg, Aschaffenburg**
- Medical Center **Albertinenkrankenhaus, Hamburg**
- Medical Center **Rotkreuzklinikum München, Frauenklinik, München**
- Medical Center **Lahn-Dill-Kliniken GmbH, Frauenklinik, Wetzlar**
- University Medical Center **Universitätsklinikum Würzburg, Würzburg**
- Medical Center **Vivantes Humboldt-Klinikum, Berlin**
- Medical Center **Vivantes Klinikum Auguste Viktoria, Berlin**
- Medical Center **HELIOS Dr. Horst Schmidt Kliniken Wiesbaden, Wiesbaden**



- Medical Center **Klinikum Wolfsburg, Wolfsburg**
- Medical Center **SRH Wald-Klinikum Gera GmbH, Gera**
- University Medical Center **Klinikum rechts der Isar, München**
- University Medical Center **Universitätsfrauenklinik Göttingen, Göttingen**
- University Medical Center **Universitätsklinikum Gießen, Gießen**
- Medical Center **Klinikum Coburg, Coburg**
- Medical Center **Klinikum Dahme-Spreewald GmbH Achenbach-Krankenhaus, Königs Wusterhausen**
- University Medical Center **Universitätsklinikum Aachen, Aachen**
- Medical Center **Kaiserswerther Diakonie Florence-Nightingale-Krankenhaus, Düsseldorf**
- Medical Center **Diakonie Klinikum Dietrich Bonhoeffer, Neubrandenburg**
- Medical Center **RoMed Kliniken Rosenheim, Rosenheim**
- Medical Center **Krankenhaus Waldfriede, Berlin**
- Medical Center **St. Vincenz-Krankenhaus GmbH, Paderborn**
- Medical Center **St. Elisabeth Krankenhaus GmbH, Köln**
- Medical Center **Klinikum Hanau GmbH, Hanau**
- Medical Center **St. Franziskus-Hospital, Münster**
- Medical Center **Universitätsklinikum Schleswig-Holstein, Lübeck**
- Medical Center **Krankenhaus St. Elisabeth und St. Barbara Halle (Saale) GmbH , Halle Saale**
- Medical Center **Krankenhaus Wermelskirchen GmbH , Wermelskirchen**
- Doctor's Practice **Bremen**
- University Medical Center **Universitätsfrauenklinik und Poliklinik am Klinikum Südstad , Rostock**
- Medical Center **HELIOS Kliniken Schwerin GmbH, Schwerin**
- Medical Center **St. Josefs Hospital, Wiesbaden**
- Medical Center **Katholisches Klinikum Mainz, Mainz**
- Doctor's Practice **Eggenfelden**
- Medical Center **Diakoniekrankenhaus Freiburg, Freiburg im Breisgau**
- Medical Center **Kathol. Marienkrankenhaus, Hamburg**
- Medical Center **HELIOS, Wuppertal**
- Medical Center **St. Johannes, Dortmund**
- Medical Center **Klinikum Chemnitz, Chemnitz**
- Medical Center **Klinikum Aschaffenburg, Aschaffenburg**

- Medical Center **Klinikum Bayreuth, Bayreuth**
- Medical Center **Johann Wolfgang Goethe-Universität, Frankfurt a.M.**
- Medical Center **Universitätsfrauenklinik Göttingen, Göttingen**
- Medical Center **Marien Hospital Witten, Witten**
- Medical Center **Kreisklinik Altötting, Altötting**
- Medical Center **Hufeland Klinikum GmbH , Bad Langensalza**
- Medical Center **Universitätsfrauenklinik Bonn , Bonn**
- Medical Center **Diakonissenkrankenhaus Mannheim, Mannheim**
- Medical Center **Kreiskliniken Reutlingen , Reutlingen**
- Medical Center **Ruhr-Universität Bochum, Herne**
- Medical Center **Klinikum Itzehoe , Itzehoe**
- Medical Center **St. Vincenz KH Limburg, Limburg**
- Medical Center **Medizinische Universität Innsbruck, Innsbruck**
- Medical Center **Kanstonsspital Baden , Baden**
- Medical Center **Marienhospital Stuttgart, Stuttgart**
- Medical Center **Hegau-Bodensee-Klinikum, Singen**
- Medical Center **Vivantes-Klinikum am Urban, Berlin**
- Medical Center **DONAUISAR Klinikum Deggendorf, Deggendorf**
- Medical Center **Kreiskliniken Reutlingen KLINIKUM AM STEINENBERG , Reutlingen**
- Medical Center **Diakonissenkrankenhaus, Mannheim**
- Medical Center **Sana Klinikum Offenbach, Offenbach am Main**
- Medical Center **Kliniken Ostalb, Mutlangen**
- Medical Center **HELIOS Amper-Klinikum, Dachau**
- Medical Center **St. Elisabeth Krankenhaus, Ravensburg**
- Medical Center **Städtisches Klinikum Brandenburg GmbH, Brandenburg an der Havel**
- Medical Center **Lukaskrankenhaus Neuss, Neuss**
- Medical Center **Christophorus Kliniken Coesfeld, Gynäkologie, Coesfeld**
- Medical Center **Evangelisches Krankenhaus Hamm gGmbH, Gynäkologie und Gynäkologische Onkologie, Hamm**
- Medical Center **Heinrich-Braun-Klinikum Zwickau, Zwickau**
- Doctor's Practice **Dresden**
- Medical Center **Städtisches Klinikum Magdeburg, Magdeburg**

- University Medical Center **Universitätsklinik für Frauenheilkunde, Geburtshilfe und Reproduktionsmedizin, Magdeburg**
- Medical Center **Helios Klinikum Erfurt, Erfurt**

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2015/10/02**
- Target Sample Size: **120**
- Monocenter/Multicenter trial: **Multicenter trial**
- National/International: **International**

Inclusion Criteria

- Gender: **Female**
- Minimum Age: **18 Years**
- Maximum Age: **no maximum age**

Additional Inclusion Criteria

1. **patients with gynecological sarcomas regardless of therapy and treatment line**
2. **Informed Consent**

Exclusion criteria

1. **Patients with non-gynecologic sarcomas**
2. **Lack of informed consent**

Addresses

■ Primary Sponsor

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Germany

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E-mail: [---]*

URL: [---]*

■ Contact for Scientific Queries

Charité Universitätsmedizin BerlinCampus VirchowKlinik für Gynäkologie



Contact for Scientific Queries

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■ **Contact for Public Queries**

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URL: **www.noggo.de**

Sources of Monetary or Material Support

■ **Private sponsorship (foundations, study societies, etc.)**

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■ **Commercial (pharmaceutical industry, medical engineering industry, etc.)**

PharmaMar

Uhlandstraße 14

10623 Berlin

Germany

Telephone: [---]*

Fax: [---]*



Commercial (pharmaceutical industry, medical engineering industry, etc.)

PharmaMar
Uhlandstraße 14
10623 Berlin
Germany

Telephone: [---]*

Fax: [---]*

E-mail: [---]*

URL: [---]*

Status

- Recruitment Status: **Recruiting ongoing**
- Reason, if "Recruitment stopped after recruiting started" or "Recruiting withdrawn before recruiting 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

* 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.