

**Trial Description****Title**

**Inhibin B - Evaluation of laboratory reference values in children and adolescents as well as a statement to validity and clinical appliance in pediatric diabetology and pediatric cancer survivors**

**Trial Acronym**

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**URL of the trial**

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**Brief Summary in Lay Language**

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**Brief Summary in Scientific Language**

**The glycopeptide hormone Inhibin B is being synthesized within the human gonadal cells.**

**Its secretion is influenced by gonadotropins and is in context with pubertal maturation in boys and girls. Therefore it is a precondition of fertility development. During maturation of the organism, comprising the development from childhood to adult, an increase in Serum concentration of inhibin B can be expected.**

**In contrast we may anticipate lower or higher values in gonadal disease or in chronic health conditions due to delayed or accelerated maturity. Pediatric oncology patients may have deviant biochemical values due to their underlying disease or altered pubertal development. We also may expect deviant values for Inhibin B as well as an altered pubertal development in patients with pediatric diabetes.**

**Cumbersome we do not have standard values concerning measurement of Inhibin B by using the assay of Beckman Coulter. The newly developed Assay „Inhibin B Gen II ELISA“ may now differentiate between structural subgroups of Inhibin B and therefore perform a more accurate measurement since before.**

**The relation to endocrine markers of pubertal development like, e.g. LH (luteinising hormone), FSH (follicle stimulating hormone) as well as to steroids DHEAS (dehydroepiandrosterone), testosterone and estrogen therefore may be evaluated more accurately concerning its role in maturation to fertility. To date studies concerning Inhibin B in pediatric patients are sparse. Here, using comparative data of Serum Inhibin B, information on pubertal development in healthy and sick children will be examined. In this study standard values for Inhibin B will be described as well as an interpretation will be given for Inhibin B in chronic health conditions of pediatric patients with diabetes mellitus and in young survivors of childhood cancer disease.**

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



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

[---]\*

### Description IPD sharing plan

[---]\*

## Organizational Data

- DRKS-ID: **DRKS00015263**
- Date of Registration in DRKS: **2018/08/27**
- 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.: **215/18 , Ethikkommission des Fachbereichs Humanmedizin der Johann-Wolfgang-Goethe-Universität Frankfurt am Main**

## Secondary IDs

## Health condition or Problem studied

- Free text: **study for standard/normal values**
- ICD10: **E10.90 - [generalization E10.9: Type 1 diabetes mellitus; Without complications]**
- ICD10: **E89.9 - Postprocedural endocrine and metabolic disorder, unspecified**
- ICD10: **Z08.9 - Follow-up examination after unspecified treatment for malignant neoplasm**

## Interventions/Observational Groups

- Arm 1: **<style fontName='DejaVu Sans' isBold='true'>other, non-interventionell, first cohort (healthy children and adolescents < 20 years), 4.7 ml blood, 1 specimen**  
**</style>**
- Arm 2: **<style fontName='DejaVu Sans' isBold='true'>other, non-interventionell, second cohort (pediatric Diabetes < 20 years), 4.7 ml blood, 1 specimen**  
**</style>**



- Arm 3: `<style fontName='DejaVu Sans' isBold='true'>other, non-interventionell, third cohort (childhood cancer survivors < 20 years), 4.7 ml blood, 1 specimen`

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## Characteristics

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

## Primary Outcome

**In this study standard values for Inhibin B will be described as well as an interpretation will be given for Inhibin B in chronic health conditions of pediatric patients with diabetes mellitus and in young survivors of childhood cancer disease. The newly developed Assay „Inhibin B Gen II ELISA“ may differentiate between structural subgroups of Inhibin B and perform a more accurate measurement since before.**

## Secondary Outcome

**[---]\***

## Countries of recruitment

- DE **Germany**

## Locations of Recruitment

- University Medical Center **KKJM, Frankfurt/Main**

## Recruitment

- Planned/Actual: **Planned**
- (Anticipated or Actual) Date of First Enrollment: **2018/10/01**
- Target Sample Size: **200**
- Monocenter/Multicenter trial: **Monocenter trial**
- National/International: **National**

## Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **no minimum age**
- Maximum Age: **20 Years**

## Additional Inclusion Criteria

### including criterias:

- **informed consent**
- **Aged < 20 years**
- **no other relevant disease**
- **patients with Diabetes mellitus**
- **patients after cancer therapy, as well as after stem cell transplantation**

## Exclusion criteria

### excluding criterias:

- **aged  $\geq$  20 years at start of study**
- **acute disease**
- **other chronic disease (HIV, Tbc)**
- **pregnancy**
- **substance abuse**
- **parents beeing unable to understand the subject of the study**
- **participation in another AMG study**

## Addresses

### ■ Primary Sponsor

**KKJM, UK FfM**  
**Mr. Dr. med. Ulrich Paetow**  
**Theodor-Stern-Kai 7**  
**60590 Frankfurt/ Main**  
**Germany**

Telephone: **069 6301 7690**

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■ **Contact for Scientific Queries**

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■ **Contact for Public Queries**

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## **Sources of Monetary or Material Support**

■ **Institutional budget, no external funding (budget of sponsor/PI)**

**Klinikum der Johann Wolfgang Goethe-Universität Frankfurt am Main**

**Theodor-Stern-Kai 7**

DRKS-ID: **DRKS00015263**

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**Germany**

Telephone: [---]\*

Fax: [---]\*

E-mail: [---]\*

URL: **www.kgu.de**

## Status

- Recruitment Status: **Recruiting planned**
- 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.