***PLEASE NOTE:*** *This trial has been registered retrospectively.*

## Trial Description

### Title

**Depressive symptoms and association with disease activity, pain and disability in juvenile patients with chronic rheumatic diseases**

### Trial Acronym

/

### URL of the trial

**http:///**

### Brief Summary in Lay Language

**All patients in pediatric rheumatologic care receive a screening for depressive symptoms with the BDI-FS (Beck Depressions-Inventar - Fast Screen for medical patients) at least yearly. Patients with depressive symptoms have the possibility to be psychologically evaluated to ascertain diagnosis of manifest depression. The groups of patient with depressive symptoms / manifest depression will be compared to the patients with a normal BDI-FS score regarding parameters listed in endpoints.**

### Brief Summary in Scientific Language

**All patientd in pediatric rheumatologic care receive a Screening for depressive symptoms with the BDI-FS at least yearly. Patients with depressive symptoms have the possibility to be psychologically evaluated to ascertain diagnosis of manifest Depression. The Groups of Patient with depressive symptoms / manifest Depression will be compared to the patients with a normal BDI-FS score to analyze associations between Depression and Parameters like Age, gender, disease activity, treatment and other Parameters.**

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

**[---]***

### Description IPD sharing plan

**[---]***

## Organizational Data

■

DRKS-ID: **DRKS00016032**

- Date of Registration in DRKS: **2019/01/10**
- Date of Registration in Partner Registry or other Primary Registry: **[---]***
- Investigator Sponsored/Initiated Trial (IST/IIT): **yes**
- Ethics Approval/Approval of the Ethics Committee: **No approval required according to EC**
- (leading) Ethics Committee Nr.: **[---]* , Ethikkommission der Ärztekammer Nordrhein**

## Secondary IDs

## Health condition or Problem studied

- Free text: **juvenile idiopathic arthritis**
- ICD10: **M08 - Juvenile arthritis**
- Free text: **other rheumatic diseases**

## Interventions/Observational Groups

- Arm 1: **Patients aged 10-18 years of all genders, who are regularly visiting pediatric rheumatologic care routinely receive a screening for depressive symptoms with the BDI-FS (Beck Depressions-Inventar - Fast Screen for medical patients) at least yearly. Patients with depressive symptoms have the possibility to be psychologically evaluated to ascertain diagnosis of manifest depression. Patient characteristics such as disease activity, therapy, gender, age, disability will be compared between patient with depressive symptoms / manifest depression will and patients with a normal BDI-FS score.**

## 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**
-

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

**Prevalence of symptoms of depressive mood and suicidal tendency in juvenile patients with chronic rheumatic disease.**
**Measured by BDI FS (Beck Depressions-Inventar - Fast Screen for medical patients) once yearly in clinical routine.**
**Prevalence of definite depression and suicidality in this patient group.**

### Secondary Outcome

**To assess correlations of depressive symptoms and definite depression with**
**o disease activity**
**o diagnosis**
**o pain**
**o disability**
**o age**
**o gender**
**o concomitant disease**
**o therapy**

## Countries of recruitment

- DE **Germany**

## Locations of Recruitment

- Medical Center **Kinderrheumazentrum, Sankt Augustin**

## Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2018/09/20**
- Target Sample Size: **300**
- Monocenter/Multicenter trial: **Monocenter trial**
- National/International: **National**

### Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **10 Years**
- Maximum Age: **18 Years**

### Additional Inclusion Criteria

**diagnosis of chronic rheumatic disease**

### Exclusion criteria

**none**

## Addresses

- **Primary Sponsor**

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## Sources of Monetary or Material Support

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

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**Donaustrasse 13**
**56567 Neuwied**
**Germany**

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

## Status

■ Recruitment Status: **Recruiting complete, follow-up complete**

■ Study Closing (LPLV): **2019/07/01**

## 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.*