

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

## Trial Description

### Title

**Lupus long-term study (LuLa) - extension of a cross-sectional study with initiation of an inception cohort**

### Trial Acronym

**LuLa**

### URL of the trial

**<http://www.lula-studie.de>**

### Brief Summary in Lay Language

**[---]\***

### Brief Summary in Scientific Language

**The study is an extension of a prospective patient-centered epidemiologic cohort-study on the course of disease of patients with systemic lupus erythematosus that we are conducting since 2001. It is non-interventional, not-experimental, and is performed as an annual postal pseudonymized survey using partly variable patient questionnaires.**

**Participants of the former study (LuLa 2001-2010) are being included as well as new entrants with disease duration of less than two years.**

**Patient-centered documentation has the advantage that the effects of the disease are gathered directly from the patient. In the past years such patient-reported data has continuously gained importance for clinical decision making as well as cost-bearers.**

**Exemplary central questions are:**

**- What are the therapeutic changes in the past 15 years of treating SLE and what importance does it have on disease activity, damage and comorbidities?**

**Which factors contribute to the burden of illness?**

**What is the importance of physical, mental and therapeutic aspects?**

**What significance has disease activity and damage?**

**Are there implications for health care costs?**

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

**[---]\***

### Description IPD sharing plan

[---]\*

## Organizational Data

- DRKS-ID: **DRKS00011052**
- Date of Registration in DRKS: **2016/10/04**
- 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.: **3708 , Ethik-Kommission an der Medizinischen Fakultät der Heinrich-Heine-Universität Düsseldorf**

## Secondary IDs

## Health condition or Problem studied

- ICD10: **M32 - Systemic lupus erythematosus**

## Interventions/Observational Groups

- Arm 1: **The study is conducted using an annual, pseudonymized postal survey with partly variable questionnaires on different aspects of disease (e.g. physical and mental quality of life, disease activity, treatment, pain, costs, damage, depression, hospitalizations, physical activity, fatigue, sleep disorders, work productivity, vaccination status).**

## Characteristics

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



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Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **N/A**

### Primary Outcome

**Quality of life (physical and mental) is surveyed annually by a validated questionnaire. Descriptive, univariable and multivariable analysis are being conducted for evaluation.**

### Secondary Outcome

**Treatment, disease activity, concomitant diseases, physical functioning, pain and disease flares are surveyed using appropriate questionnaires and analyzed annually. Other secondary endpoints are analyzed sporadic due to annually changing focus topics in the survey (e.g. costs, damage, depression, hospitalizations, physical activity, fatigue, sleep disorders, work productivity, vaccination status). Descriptive, univariable and multivariable analysis are being conducted.**

### Countries of recruitment

- **DE Germany**

### Locations of Recruitment

- **University Medical Center Rheumatologie, LuLa-Studie; Universitätsklinik Düsseldorf, Moorenstr. 5, 40225 Düsseldorf, Telefonische Studienhotline (donnerstags 9-12Uhr): 0211-811-8068; E-Mail: LuLa-Studie@rheumanet.org, Düsseldorf**
- **other Lupus Erythematoses Selbsthilfegemeinschaft e.V., Döppersberg 20, 42103 Wuppertal, Tel.: 0202/496 87 97, E-Mail: lupus@rheumanet.org, Wuppertal**



## Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2011/12/22**
- Target Sample Size: **700**
- Monocenter/Multicenter trial: **Monocenter trial**
- National/International: **National**

## Inclusion Criteria

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

## Additional Inclusion Criteria

- **Return of the questionnaire**  
**AND**
- **Diagnosis of systemic lupus erythematosus by a physician**

## Exclusion criteria

**Not being able to read or fill in paper questionnaires.**

## Addresses

### ■ Primary Sponsor

**Heinrich-Heine Universität Düsseldorf  
Moorenstraße 5  
40225 Düsseldorf  
Germany**

Telephone: [---]\*

Fax: [---]\*

E-mail: [---]\*

URL: [---]\*

### ■ Contact for Scientific Queries

**Policlinic for Rheumatology & Hiller Research Centre for Rheumatology;  
Heinrich-Heine University Duesseldorf  
Mr. Dr. med. Gamal Chehab  
Moorenstraße 5  
40225 Düsseldorf  
Germany**



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Heinrich-Heine University Duesseldorf  
Mr. Dr. med. Gamal Chehab  
Moorenstraße 5  
40225 Düsseldorf  
Germany**

Telephone: **0211-8117845**

Fax: [---]\*

E-mail: **LuLa-Studie at rheumanet.org**

URL: [---]\*

### ■ Contact for Public Queries

**Policlinic for Rheumatology & Hiller Research Centre for Rheumatology;  
Heinrich-Heine University Duesseldorf  
Mr. Dr. med. Gamal Chehab  
Moorenstr. 5  
40225 Duesseldorf  
Germany**

Telephone: **0211/8118068**

Fax: [---]\*

E-mail: **LuLa-Studie at rheumanet.org**

URL: [---]\*

### ■ Collaborator, Other Address

**Lupus Erythematodes Selbsthilfegemeinschaft e.V.  
Döppersberg 20  
42103 Wuppertal  
Germany**

Telephone: **0202/4968797**

Fax: [---]\*

E-mail: **lupus at rheumanet.org**

URL: [---]\*

## Sources of Monetary or Material Support

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

**GlaxoSmithKline GmbH & Co. KG  
Theresienhöhe 11  
80339 München  
Germany**

Telephone: [---]\*



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

**GlaxoSmithKline GmbH & Co. KG**

**Theresienhöhe 11**

**80339 München**

**Germany**

Telephone: [---]\*

Fax: [---]\*

E-mail: [---]\*

URL: [---]\*

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

**UCB Pharma, S.A.**

**Allée de la Recherche 60**

**1070 Brüssel**

**Belgium**

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.