DRKS-ID: DRKS00012318
Date of Registration in DRKS: 2017/05/17
Date of Registration in Partner Registry or other Primary Registry: [---]*

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

**Trial Description**

**Title**
Development and Validation of disease-specific Quality of Life Questionnaires for patients with chronic inducible urticaria

**Trial Acronym**
n.a.

**URL of the trial**
[---]*

**Brief Summary in Lay Language**

Background: The chronic inducible urticaria is a subgroup of chronic urticaria. In chronic inducible urticaria, wheals, skin redness, and itching on the skin are triggered by external factors (e.g. effort, pressure, friction, cold, heat, light, vibration). About 0.1-0.2% of the general population is affected. The urticaria factitia (triggered by friction), the cold urticaria (caused by cold contact) and the cholinergic urticaria (caused by physical exertion and / or passive heating) are the three most common forms of the chronic inducible urticaria. The complaints show a great variability in the intensity of the symptoms. In addition to itching, skin redness and wheals, angioedema (deep swelling in the skin) can occur. Until now, the therapy of chronic inducible urticaria is avoiding the triggering factors, but it has often been insufficient, as well as a symptom-relieving treatment, e.g. with H1-antihistamines (often called antiallergic drugs).

Aim: The assessment of disease activity and quality of life of the affected patients is important for a better assessment of the disease situation and treatment results, to be able to adapt the therapy to the individual patient in a better way and to assess the progress of the disease and the quality of life of the patients. Until now this is only possible to a very limited extent, because there is no reliable disease-specific questionnaire for this purpose. The aim of the present project is to develop disease-specific questionnaire instruments for the detection of the disease activity and quality of life of patients with chronic inducible urticaria.

**Brief Summary in Scientific Language**

The planned survey is a patient survey without invasive examinations. Background: The chronic inducible urticaria (CIndU) is a subgroup of chronic urticaria. At the CIndU, wheals, skin redness and itching on the skin are triggered by external factors (effort, pressure, friction, cold, heat, light, vibration). About 0.1-0.2% of the general population is affected by a CIndU. The urticaria factitia (triggered by friction), the cold urticaria (caused by cold contact) and the cholinergic urticaria (caused by physical exertion and / or passive heating) are the three most common forms of the chronic inducible urticaria. The complaints show a great variability in the intensity of the symptoms. In addition to itching, skin
redness and wheals, angioedema can occur. Until now, the therapy of chronic inducible urticaria is avoiding the triggering factors, but it has often been insufficient, as well as a symptom-relieving treatment, e.g. with H1-antihistamines. The assessment of disease activity and quality of life of the affected patients is important to make treatment results detectable, to be able to adapt the therapy to the individual patient in a better way and to assess the progress of the disease and the quality of life of the patients. Until now this is only possible to a very limited extent, because there is no reliable disease-specific instrument for this purpose.

**Aim:** The aim of the present project is to develop disease-specific questionnaire instruments for the detection of the disease activity and quality of life of patients with chronic inducible urticaria.

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

[---]*

**Description IPD sharing plan**

[---]*

**Organizational Data**

- **DRKS-ID:** DRKS00012318
- **Date of Registration in DRKS:** 2017/05/17
- **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.:** EA1/385/13, Ethik-Kommission der Charité - Universitätsmedizin Berlin-

**Secondary IDs**

- **ICD10:** L50.5 - Cholinergic urticaria
- **ICD10:** L50.3 - Dermatographic urticaria
- **ICD10:** L50.2 - Urticaria due to cold and heat
- **ICD10:** L50.4 - Vibratory urticaria

**Interventions/Observational Groups**
Arm 1: **Patients with chronic inducible urticaria are asked to document their impairment in different aspects of their quality of life.**

### Characteristics

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

### Primary Outcome

**Development of quality of life instruments for the subgroups of chronic inducible urticaria**

### Secondary Outcome

N/A

### Countries of recruitment

- DE Germany

### Locations of Recruitment

- Medical Center **Charite-Universitätsmedizin Berlin, Berlin**
- Medical Center **Universitätsklinik Mainz, Mainz**

### Recruitment

- **Planned/Actual:** Actual
- **(Anticipated or Actual) Date of First Enrollment:** 2014/05/07
- **Target Sample Size:** 900
- **Monocenter/Multicenter trial:** Multicenter trial
Planned/Actual: **Actual**
(Anticipated or Actual) Date of First Enrolment: **2014/05/07**
Target Sample Size: **900**
Monocenter/Multicenter trial: **Multicenter trial**
National/International: **National**

### Inclusion Criteria

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

### Additional Inclusion Criteria

chronic inducible urticaria

### Exclusion criteria

Younger than 18 years

### Addresses

**Primary Sponsor**

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Sources of Monetary or Material Support

Private sponsorship (foundations, study societies, etc.)

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Private sponsorship (foundations, study societies, etc.)

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URL: http://i2deal.net/

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.