



PLEASE NOTE: This trial has been registered retrospectively.

Trial Description

Title

"Lebenschancen" with type 1 diabetes

Trial Acronym

life chances

URL of the trial

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Brief Summary in Lay Language

Representative cross-sectional study on "life chances" among young adults (18 - 30 yrs) with type 1 diabetes diagnosed before 18 yrs of age.

Life chances include physical and psychological health and well-being, professional integration, social integration, partnership, children and satisfaction with outpatient care.

Young adults diagnosed before age of 6 yrs are compared with the ones diagnosed with diabetes between 6 and < 12 yrs and 12 - < 18 yrs of age. Furthermore the data of the young adults with diabetes are compared - if possible und not diabetes specific with the ones of the background population in Lower Saxony.

The questionnaires are completed anonymously during the out-patient visit in one of the 26 participating specialized diabetes practices.

Brief Summary in Scientific Language

Assessment of metabolic and psychosocial outcomes and life chances in a representative sample of young adults in lower saxony.

Organizational Data

- DRKS-ID: **DRKS00004870**
- Date of Registration in DRKS: **2013/04/05**
- 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.: **999-2011 , Ethikkommission der Medizinischen Hochschule Hannover**

Secondary IDs

Health condition or Problem studied

- ICD10: **E10 - Insulin-dependent diabetes mellitus**

Interventions/Observational Groups

- Arm 1: **Young adults with type 1 diabetes (age 18 - 30 yrs) with diabetes onset before 18th birthday once complete a structured questionnaire on therapy regimen, metabolic control, quality of life, psychosocial situation and satisfaction with therapy. Participants diagnosed before 6 yrs of age are compared with those diagnosed between 6 -< 12 yrs of age and those diagnosed between 12 and < 18 yrs of age. These data will be compared - if possible and not diabetes specific - with those of healthy controls of the same age range. (Statistics Lower Saxony).**
- Arm 2: **Control group: Statistical data of the background population (same age range, living in Lower Saxony)**

Characteristics

- Study Type: **Non-interventional**
- Study Type Non-Interventional: **Observational study**
- Allocation: **Non-randomized controlled trial**
- Blinding: **Open (masking not used)**
- Who is blinded: [---]*
- Control: **Other**
- Purpose: **Prognosis**
- Assignment: **Other**
- Phase: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **N/A**

Primary Outcome

One-time answering of the following structured questionnaires

- 1) on metabolic control**
- 2) on insulin regimen**
- 3) psychological well-being WHO-5 (WHO-Five Wellbeing index)**
- 4) Depression / Anxiety (HADS) (Hospital Anxiety and Depression Scale- German version)**

- 5) diabetesspecific burden (PAID) (Problem Areas in Diabetes Questionnaire)**
- 6) satisfaction with therapy (5 Items; rating scale 1 - 6 on different aspects of diabetes long-term care)**
- 7) sociodemographic data**

Secondary Outcome

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Countries of recruitment

- DE **Germany**

Locations of Recruitment

- Doctor's Practice **Niedersachsen**

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2011/10/03**
- Target Sample Size: **320**
- Monocenter/Multicenter trial: **Multicenter trial**
- National/International: **National**

Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **18 Years**
- Maximum Age: **30 Years**

Additional Inclusion Criteria

Type 1 diabetes diagnosed before age of 18 yrs and age between 18 and 30 yrs. and diabetes out-patient care in Lower Saxony.

Controls: young adults (18-30 yrs) living in Lower Saxony

Exclusion criteria

no agreement with participation

Addresses

■ Primary Sponsor

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■ Contact for Scientific Queries

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Sources of Monetary or Material Support

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

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URL: **<http://www.diabetesstiftung.de/index.php?id=115>**

Status

- Recruitment Status: **Recruiting complete, follow-up complete**
- Study Closing (LPLV): **2013/04/03**

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.