

# Effect of therapy on residual beta cell function in type-1 diabetes mellitus

<b>Submission date</b> 03/10/2002	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 03/10/2002	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 05/09/2007	<b>Condition category</b> Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

**Plain English summary of protocol**  
Not provided at time of registration

## Contact information

**Type(s)**  
Scientific

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## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**  
N/A

# Study information

## Scientific Title

## Study objectives

1. Under consideration of baseline data the difference of C-peptide levels between patients under intensive therapy and conventional therapy depends on the willingness of the patients to take part in such a clinical study
2. The failure rate of intensive therapy is less than the rate of conventional therapy

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

Not provided at time of registration

## Study design

Randomised controlled trial

## Primary study design

Interventional

## Secondary study design

Randomised controlled trial

## Study setting(s)

Not specified

## Study type(s)

Treatment

## Participant information sheet

## Health condition(s) or problem(s) studied

Type 1 diabetes mellitus

## Interventions

Conventional or intensive insulin therapy

## Intervention Type

Other

## Phase

Not Specified

## Primary outcome measure

Not provided at time of registration

## Secondary outcome measures

Not provided at time of registration

**Overall study start date**

01/01/2003

**Completion date**

01/01/2005

## **Eligibility**

**Key inclusion criteria**

1. Men or women aged 18 - 40 years at diagnosis
2. Established Type-1 Diabetes diagnosed up to three months ago
3. Consent to participate in a diabetes training programme
4. Informed consent before enrolment

**Participant type(s)**

Patient

**Age group**

Not Specified

**Sex**

Not Specified

**Target number of participants**

Not provided at time of registration

**Key exclusion criteria**

1. History of neuropathy, nephropathy, and retinopathy of other than diabetes related origin
2. Negative C-peptide level at diagnosis
3. History of psychiatric disease or drug or alcohol abuse
4. Treatment with oral antidiabetic medication
5. Subject unlikely to comply with the protocol (e.g. inability or unwillingness to participate adequate training or to complete diaries appropriately) or to understand the nature and the scope of the study

**Date of first enrolment**

01/01/2003

**Date of final enrolment**

01/01/2005

## **Locations**

**Countries of recruitment**

Germany

**Study participating centre**  
**Clinical Research Unit**  
Giessen, Rodthohl 6  
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D-35385

## **Sponsor information**

**Organisation**  
Justus Liebig University (Germany)

### **Sponsor details**

-  
Giessen Rodthohl 6  
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D-35385

**Sponsor type**  
University/education

**ROR**  
<https://ror.org/033eqas34>

## **Funder(s)**

**Funder type**  
University/education

**Funder Name**  
Justus Liebig University (Germany)

## **Results and Publications**

**Publication and dissemination plan**  
Not provided at time of registration

**Intention to publish date**

**Individual participant data (IPD) sharing plan**

**IPD sharing plan summary**

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Protocol article</a>	Protocol	10/12/2003		Yes	No