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

Submission date	Recruitment status No longer recruiting	[X] Prospectively registered	
03/10/2002		[X] Protocol	
Registration date	Overall study status	Statistical analysis plan	
03/10/2002	Completed Condition category	Results	
Last Edited		Individual participant data	
05/09/2007	Nutritional, Metabolic, Endocrine	Record updated in last year	

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

Protocol serial number 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

Study type(s)

Treatment

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(s)

Not provided at time of registration

Key secondary outcome(s))

Not provided at time of registration

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

Healthy volunteers allowed

No

Age group

Not Specified

Sex

Not Specified

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 alc ohol 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 Germany D-35385

Sponsor information

Organisation

Justus Liebig University (Germany)

ROR

https://ror.org/033eqas34

Funder(s)

Funder type

University/education

Funder Name

Justus Liebig University (Germany)

Results and Publications

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?
Protocol article	Protocol	10/12/2003		Yes	No