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

Submission date	Recruitment status	[X] Prospectively registered
03/10/2002	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
03/10/2002	Completed	[_] Results
Last Edited	**Condition category**	[_] 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

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Additional identifiers

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

Primary study design
Interventional

Study design
Randomised controlled trial

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