ISRCTN29335793 https://doi.org/10.1186/ISRCTN29335793

Insulin combination therapy in type 2 diabetes

Submission date
19/07/2006

Recruitment status
No longer recruiting

Registration date
19/07/2006

Overall study status
Completed

Last Edited
19/07/2006

Condition category
Nutritional, Metabolic, Endocrine

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] 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

Acronym
DIASULIN

Study objectives

Continuing sulfonylurea in patients without good glycaemic control and using insulin and metformin, will diminish insulin secretion of beta-cells, less than discontinuing sulfonylurea in these patients.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Primary study design
Interventional

Study design
Randomised controlled, parallel group trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Diabetes mellitus type 2 (DM type II)

Interventions
Continuing sulfonylurea with a combination of metformin and insulin glargine versus discontinuing sulfonylurea with this combination.

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Metformin, sulfonylurea, insulin glargine

Primary outcome(s)
Difference between the two groups in the remaining insulin secretion of the beta-cells, assessed by differences in Homeostasis Model Assessment (HOMA)-beta and in fasting C-peptide.

Key secondary outcome(s)
1. Difference in mean daily dosage of insulin glargine in order to reach good glycaemic control (HbA1c <= 7.0%)
2. Percentage of patients with good glycaemic control after 12 months
3. Percentage of patients with good glycaemic control at several intervals within 12 months
4. Frequency of serious and of nocturnal hypoglycaemic episodes
5. Waist circumference
6. Quality of life
7. Patients' treatment satisfaction

Completion date
01/04/2007

Eligibility

Key inclusion criteria
1. Type 2 diabetes patients, male and female, insulin naive, without good glycaemic control for at least three months despite combination of metformin and sulfonylurea therapy and who are referred for insulin therapy by their general practitioner (GP)
2. Aged 40-75 years
3. Haemoglobin HbA1c (HbA1c) >=7.5%

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
1. Type 1 diabetes
2. C-peptide <0.50 nmol/l
3. Liver (aspartate aminotransferase [AST] or alanine aminotransferase [ALT] >2 times upper limit of normal) and/or kidney (creatinine >135 in male patients, >110 in female patients) problems
4. Patients who do not read Dutch well enough to answer questionnaires
5. Pregnancy or lactation
6. Amputated leg or arm
7. Intercurrent disease at the discretion of the investigator
8. Short life expectancy
9. Contraindications or intolerancy to metformin, sulfonylurea or insulin glargine

Date of first enrolment
01/04/2006

Date of final enrolment
01/04/2007

Locations

Countries of recruitment
Netherlands

Study participating centre

University Medical Center Utrecht (UMCU)
Utrecht
Netherlands
3508 GA

Sponsor information

Organisation
Stichting Julius Research (The Netherlands)

ROR
https://ror.org/0575yy874

Funder(s)

Funder type
Industry

Funder Name
Sanofi-Aventis

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration