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Insulin combination therapy in type 2 diabetes

Submission date	Recruitment status	[ ] Prospectively registered
19/07/2006	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
19/07/2006	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
19/07/2006	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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

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

Study design
Randomised controlled, parallel group 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
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 measure
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.

Secondary outcome measures
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

Overall study start date
01/04/2006

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

Age group
Adult

Sex
Both

Target number of participants
200

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)
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Sponsor information

Organisation
Stichting Julius Research (The Netherlands)

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Sponsor type
Research organisation

ROR
https://ror.org/0575yy874

Funder(s)

Funder type
Industry

Funder Name
Sanofi-Aventis

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