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INITIATE (INITiate Insulin by Aggressive Titration and Education): a randomised study to compare initiation of insulin combination therapy in type two diabetic patients individually and in groups

Submission date	Recruitment status
08/11/2006	No longer recruiting
Registration date	**Overall study status**
14/11/2006	Completed
Last Edited	**Condition category**
25/09/2009	Nutritional, Metabolic, Endocrine

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

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
HOE901/4041

Study information

Scientific Title

Acronym
INITIATE (INITiate Insulin by Aggressive Titration and Education)

Study objectives
To compare initiation of insulin Individually (IND) and in Groups (GROUP) with respect to change in HbA1c and several other parameters in type two diabetic patients.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Study approved by the Ethics Committee of Helsinki University Hospital (Finland) on August 15, 2003.

Study design
Multicentre multinational randomised open study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Type 2 diabetes

Interventions
Insulin glargine initiated by group education versus insulin glargine initiated by teach each individual patient.

Intervention Type
Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)
Insulin glargine

Primary outcome measure
To determine whether insulin therapy with insulin glargine can be initiated as effectively by group education as by teaching each patient individually. Programs are defined as equally successful if the HbA1c differs less than 0.5% at the end of the study.

Secondary outcome measures
1. Cost of initiation of insulin therapy including: time spent by a nurse on education, physicians time, number and duration of phone calls
2. Change in the concentrations of serum total, High Density Lipoproteins (HDL) and Low Density Lipoproteins (LDL) cholesterol, and serum triglycerides (visit 12 versus visit three)
3. Change in body weight and blood pressure (visit 12 versus visit three)
4. Change in the fasting plasma glucose concentration (visit 12 versus visit three)
5. Insulin dose at visit 12
6. Change in subjects treatment satisfaction (measured by the Diabetes Treatment Satisfaction Questionnaire [DTSQ]) (visit 12 versus visit three)

Overall study start date
17/11/2003

Completion date
21/06/2005

Eligibility

Key inclusion criteria
1. Male or female patients aged greater or equal to 18 years of age with type two diabetes
2. Treated with a stable dose (any dose) of sulfonylurea and metformin (1.5 grams or more) or either drug alone for at least six months
3. Body Mass Index (BMI) less than 45 kg/m^2
4. HbA1c between 7.0 and 12%
5. Willingness and ability to inject insulin and perform self-monitoring of blood glucose and to share some health information (glycemic control and body weight) with other members of the group

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
120

Key exclusion criteria
1. Insulin therapy during the preceding 12 months
2. Impaired renal function, as shown by (but not limited to) serum creatinine more than 177 µmol /L (more than 2.0 mg/dL) measured at visit one or current renal dialysis
3. Gross proteinuria (dU-prot more than 3 g) at screening
4. Known acute or chronic metabolic acidosis, including diabetic ketoacidosis
5. Clinical evidence of active liver disease, or serum Alanine Aminotransferase (ALT) more than 2.5 times the upper limit of the normal range
6. History of hypoglycemia unawareness
7. Repeated (more than one) severe hypoglycemia with unconsciousness within the last year
8. Diabetic retinopathy with surgical treatment (laser photocoagulation or vitrectomy) during the preceding three months of study entry, or requiring treatment within three months after the study entry
9. Pregnancy or lactation
10. Failure to use adequate contraception (women of current reproductive potential only), e.g. use of systemic hormones (oral contraceptives or an implant), an intrauterine device, or a barrier method (diaphragm with intravaginal spermicide, cervical cap, male or female condom)
11. Known hypersensitivity to insulin glargine, or any of the excipients
12. Malignancy (except for basal cell skin cancer) within the last five years
13. Likelihood of requiring treatment during the study period with drugs not permitted by the study protocol (e.g. non-cardioselective Beta-blockers, systemic corticosteroids, thiazolidinediones) months
14. Known adrenal insufficiency
15. Known haemoglobinopathy or moderate to severe anemia (i.e. hemoglobin concentration less than 110 g/dl)
16. Psychiatric condition rendering the subject unable to understand the nature, scope, and possible consequences of the study
17. History of substance or alcohol abuse within the last two years, or current substance abuse
18. Inability to comply with study procedures
19. Any clinically relevant cardiovascular, hepatic, neurological, endocrine, or other major systemic disease making implementation of the protocol or interpretation of the study results difficult
20. Known positive test result for Glutamic Acid Decarboxylase (GAD), or islet cell antibodies
21. Type one Diabetes Mellitus, as defined by the World Health Organisation (WHO)
22. Use of an investigational drug during the last six months before study entry
23. Inability to stop current treatment with thiazolidinedione

Date of first enrolment
17/11/2003

Date of final enrolment
21/06/2005

Locations

Countries of recruitment
Finland

Netherlands

Sweden

United Kingdom

Study participating centre
Department of Medicine
Helsinki
Finland
FIN-00029

Sponsor information

Organisation
sanofi-aventis Oy (Finland)

Sponsor details
c/o Sanni Lahdenpera
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Sponsor type
Industry

Website
http://en.sanofi-aventis.com/

ROR
https://ror.org/00tx8br33

Funder(s)

Funder type
Industry

Funder Name
Sanofi-Aventis (Finland)

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?
Results article	results	01/06/2007		Yes	No