

# 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**

08/11/2006

**Recruitment status**

No longer recruiting

**Registration date**

14/11/2006

**Overall study status**

Completed

**Last Edited**

25/09/2009

**Condition category**

Nutritional, Metabolic, Endocrine

☐ Prospectively registered

☐ Protocol

☐ Statistical analysis plan

☒ Results

☐ Individual participant data

**Plain English summary of protocol**

Not provided at time of registration

## Contact information

**Type(s)**

Scientific

**Contact name**

Prof Hannele Yki-Jarvinen

**Contact details**

Department of Medicine  
University of Helsinki  
P.O. Box 700  
Helsinki  
Finland  
FIN-00029

## Additional identifiers

**Protocol serial number**

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.

### **Primary study design**

Interventional

### **Study design**

Multicentre multinational randomised open study

### **Study type(s)**

Treatment

### **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(s)**

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.

### **Key secondary outcome(s)**

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)

**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<sup>2</sup>
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

**Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

18 Years

**Sex**

All

**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**

United Kingdom

Finland

Netherlands

Sweden

**Study participating centre**

**Department of Medicine**

Helsinki

Finland

FIN-00029

# Sponsor information

## Organisation

sanofi-aventis Oy (Finland)

## ROR

<https://ror.org/00tx8br33>

# Funder(s)

## Funder type

Industry

## Funder Name

Sanofi-Aventis (Finland)

# 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? |
|---------------------------------|---------|--------------|------------|----------------|-----------------|
| <a href="#">Results article</a> | results | 01/06/2007   |            | Yes            | No              |