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32-week, multicentre, open, randomised, two-way cross-over, clinical trial comparing insulin glargine (HOE 901) in combination with insulin lispro and neutral protamine Hagedorn in combination with regular human insulin in subjects with type one diabetes mellitus on a meal-time and basal insulin regimen

Submission date
21/02/2007

Recruitment status
No longer recruiting

Registration date
17/04/2007

Overall study status
Completed

Last Edited
27/10/2022

Condition category
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

Protocol serial number
HOE 901/4006

Study information

Scientific Title
32-week, multicentre, open, randomised, two-way cross-over, clinical trial comparing insulin glargine (HOE 901) in combination with insulin lispro and neutral protamine Hagedorn in combination with regular human insulin in subjects with type one diabetes mellitus on a meal-time and basal insulin regimen

Acronym
The Home Study

Study objectives
Insulin glargine plus insulin lispro improves blood glucose control in people with type one diabetes as assessed by HbA1c compared to Neutral Protamine Hagedorn (NPH) insulin plus unmodified human insulin.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approval received from local Multicentre Research Ethics Committee (MREC) in December 2000 (ref: 0/3/56).

Study design
Open, randomised, two-way cross-over trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Type one diabetes mellitus

Interventions
Insulin glargine plus insulin lispro in one arm of study, NPH insulin plus unmodified human insulin in other arm.

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)

Insulin glargine, insulin lispro, NPH insulin, unmodified human insulin

Primary outcome(s)
HbA1c at end of treatment period.

Key secondary outcome(s))
1. Insulin doses
2. Pre-breakfast SMBG concentration
3. 24-hour eight-point SMBG levels
4. 24-hour in-patient plasma glucose levels
5. Monthly rate of hypoglycaemia

Completion date
01/09/2002

Eligibility

Key inclusion criteria
1. Men and women, aged 18 to 65 years
2. Type one diabetes mellitus as shown by C-peptide deficient status (less than 0.10 nmol/L when plasma glucose is greater than 4.5 mmol/L)
3. More than one year on a daily multiple insulin injection regimen
4. Experience in Self Monitoring of Blood Glucose (SMBG), interpretation of SMBG results and insulin dose adjustments
5. HbA1c greater than 7.0% and less than 9.5% at visit one
6. Willingness to actively adjust the insulin doses in order to achieve the target blood glucose levels and to perform SMBG profiles using the Accutrend Sensor Complete on a regular basis as specified in the study protocol
7. Women of childbearing potential are to be using adequate contraceptive protection

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
1. Treatment with blood-glucose-lowering drugs other than insulin in the last eight weeks before screening visit (visit one)
2. Use of an investigational drug other than insulin in the last six months before study entry, or use of an investigational insulin in the last four weeks before study entry

3. Diabetic retinopathy with surgical treatment (laser photocoagulation or vitrectomy) in the three months before study entry or which may require surgical treatment within three months of study entry as evidenced by retino-screening within the last 12 months
4. History of repeated severe hypoglycaemia with unconsciousness within the last two years
5. Night shift workers
6. Pancreatectomised subjects
7. Clinically relevant cardiovascular, hepatic, neurologic, endocrine, or other major systemic disease making implementation of the protocol or interpretation of the study results difficult
8. History of drug or alcohol abuse
9. Pregnant (as determined by pregnancy blood test at visit one) or breast-feeding women
10. Impaired hepatic function, as shown by but not limited to Serum Glutamic Pyruvic Transaminase (SGPT) (ALanine AminoTransferase
[ALAT]) or Serum Glutamic-Oxaloacetic Transaminase (SGOT) (ASpartate AminoTransferase [ASAT]) above 2 x the upper limit of normal measured at visit one
11. Impaired renal function, as shown by but not limited to serum creatinine greater than 177 µmol/L (greater than 2.0 mg/dL) measured at visit one
12. Mental condition rendering the subject unable to understand the nature, scope and possible consequences of the study
13. Evidence of an uncooperative attitude
14. Inability to attend clinical visits
15. Known employee of sanofi-aventis

Date of first enrolment
01/02/2001

Date of final enrolment
01/09/2002

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
School of Clinical Medical Sciences - Diabetes
Newcastle upon Tyne
United Kingdom
NE2 4HH

Sponsor information

Organisation
Sanofi-aventis (UK)

ROR
https://ror.org/05bf2vj98

Funder(s)

Funder type
Industry

Funder Name
Sanofi-aventis (UK)

Results and Publications

Individual participant data (IPD) sharing plan
Not provided at time of registration

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		01/03/2006		Yes	No
Results article		01/06/2008		Yes	No