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Multicentre clinical study of the efficacy and safety of INHaled INSulin aerosol in the treatment of type 2 diabetes

Submission date
20/10/2007

Recruitment status
No longer recruiting

Registration date
16/11/2007

Overall study status
Completed

Last Edited
08/08/2008

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

Protocol serial number
C20030218

Study information

Scientific Title

Acronym

INH-INS

Study objectives
Inhaled insulin plus a single injection of insulin glargine can provide glycaemic control comparable to a conventional subcutaneous insulin regimen in type 2 diabetes patients who previously managed with at least two daily subcutaneous injections of insulin.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval received from the First Affiliated Hospital of Sun Yatsen University on the 1st July 2005.

Study design
A randomised, open-labelled, parallel controlled study

Primary study design
Interventional

Study type(s)
Treatment

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

Interventions
This is a randomised, open-labeled, parallel control study, consists of a screening visit, a 2-week baseline lead-in phase, and a 12-week treatment phase. All subjects received insulin glargine at bedtime as basal insulin supply in the two phases. During the baseline period, all subjects received subcutaneous regular human insulin (RI) injections at 30 minutes before each meal (3 times per day). Then, during the treatment phase, the patients were randomised to receive an inhaled insulin regimen or continue receiving RI subcutaneous therapy as the run-in phase. Inhaled Insulin aerosol capsular (Inh-Ins) was given at 10 minutes before each meal (3 times per day), each capsule contained 40 IU insulin. All patients followed the instruction of diet, exercise and self monitoring of blood glucose (SMBG). The dose of insulins was adjusted at the discretion of the investigator, based on SMBG results, to achieve target of 4.4 - 7.8 mmol/L for fasting or pre-meal, less than 10 mmol/L for postprandial, 5.6 - 8.9 mmol/L before bedtime. Hypoglycaemia should be avoided as much as possible.

The insulin dosage is varied from patient to patient. At the end of the study, in the treatment group, the mean dose of Inh-Ins was about 240 IU per day, and in control group, the mean dose of RI was about 27 IU per day.

The total duration of both treatment lasted for 12 weeks, and the follow-up for all treatment arms was 16 weeks (4 more weeks after the treatment).

Intervention Type
Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)
Insulin aerosol, insulin glargine

Primary outcome(s)
The change in HbA1c from baseline until week 12.

Key secondary outcome(s))
1. The change of FPG from baseline until week 8 and week 12
2. 1-hour and 2-hour postprandial blood glucose (1hPBG and 2hPBG) response, using a standardised breakfast (330 Kcal of Glucerna-SR)

Completion date
05/07/2006

Eligibility

Key inclusion criteria
Men and women (n = 253) diagnosed with type 2 diabetes were screened out at five centres in China. Inclusion criteria were:
1. Aged 18 to 65 years
2. Stable subcutaneous insulin schedule involving two to three injections daily for at least 2 months before study entry and not receiving any oral antidiabetic agents for at least 1 month
3. Screening and pre-randomisation fasting plasma glucose (FPG) values not more than 13mmol /L, body mass index (BMI) 18 - 28 kg/m^2
3. Written informed consent

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
1. Asthma
2. Chronic obstructive pulmonary disease or other significant respiratory disease
3. Smoking during the last 6 months
4. Abnormal screening chest X-ray
5. Abnormal pulmonary function at screening (carbon monoxide diffusing capacity [DLCO] less than 75%, total lung capacity [TLC] less than 80 or greater than 120%, and forced expiratory

volume in one second [FEV1] less than 70% of predicted)
6. Major organ system disease
7. Clinically significant abnormalities on laboratory screening
8. Concomitant therapy with systemic glucocorticoids
9. Any inhaled insulin clinical trial previously
10. A daily insulin requirement of greater than 1.0 U/Kg

Date of first enrolment
22/08/2005

Date of final enrolment
05/07/2006

Locations

Countries of recruitment
China

Study participating centre
Dept of Endocrinology
Guangzhou
China
510080

Sponsor information

Organisation
Chuangxinhui Biotech Venture Capital Co., Ltd (China)

Funder(s)

Funder type
Industry

Funder Name
Chuangxinhui Biotech Venture Capital Co. Ltd (China)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration