

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	<input type="checkbox"/> Prospectively registered
Registration date 16/11/2007	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 08/08/2008	Condition category Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Prof Jianping Weng

Contact details

Dept of Endocrinology
First Affiliated Hospital of Sun Yatsen University
Guangzhou
China
510080

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

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

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 measure

The change in HbA1c from baseline until week 12.

Secondary outcome measures

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)

Overall study start date

22/08/2005

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/m²
3. Written informed consent

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

252

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)

Sponsor details

Kai Yuan Building, Room 2210-2212

Bei Huan Da Dao, No 7001

Shenzhen

China

518000

Sponsor type

Industry

Funder(s)

Funder type

Industry

Funder Name

Chuangxinhui Biotech Venture Capital Co. Ltd (China)

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