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Switch to oral hypoglycemic agent therapy from insulin injection in patients with type 2 diabetes

Submission date	Recruitment status	[_] Prospectively registered
10/08/2007	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
17/08/2007	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
29/10/2021	Nutritional, Metabolic, Endocrine	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Study information

Scientific Title
Switch to oral hypoglycemic agent therapy from insulin injection in patients with type 2 diabetes

Study objectives

Insulin injection treatment is associated with pain and puts a heavy physical, mental, and financial burden on patients. In this study, we aim to develop a novel method to change the route of administration of hypoglycemic agents from needle-mediated to oral, thereby enabling patients with type 2 diabetes to have a more comfortable life by being liberated from painful procedures and recurrent insulin-induced hypoglycemic incidents. Pioglitazone is a newly available agent that improves insulin resistance, a core defect in type 2 diabetes. Since pioglitazone has not been used as a major agent for switching, this study uses this agent together with a sulphonylurea, glimepiride and an alpha glucosidase inhibitor, voglibose to develop a new approach for the substitution of insulin therapy. Since insulin injection per se may exacerbate insulin resistance, we completely stop insulin injections before the switch and then immediately administer oral agents in patients under long-term insulin injection in order to maximize pioglitazone's insulin-sensitizing capacity.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Kitami Medical Association Institutional Review Board, approved on 03/07/2006 (ref: 06-B-108)

Primary study design
Interventional

Study design
Non-randomised controlled trial (all participants received the same interventions and there was no control group).

Study type(s)
Treatment

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

Interventions
All participants are hospitalized. On the day insulin injection therapy is completely withdrawn, the therapy with oral hypoglycemic agents (combination therapy) is initiated.

The initial doses are: 15-30 mg Pioglitazone ,1-3 mg glimepiride, and 0.9 mg voglibose. The maximum dose of pioglitazone is 45 mg, and that of glimepiride is 4 mg. If fasting plasma glucose is less than 5.55 mmol/l and/or hypoglycemia developed, glimepiride is first reduced in dosage and then pioglitazone.

Duration of interventions: 4 months.

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)

pioglitazone, glimepiride and voglibose

Primary outcome(s)
Rate of success in the study. Success is defined as HbA1c at four months after the switch <7.0%.

Key secondary outcome(s)
Difference in mean HbA1C from the baseline compared to four-month timepoint. Differences among values of the following are also assessed (measured at months 0 and 4):

1. Serum lipid concentrations
2. Blood pressure
3. Body weight
4. Hematocrit
5. Albumin
6. Blood urea nitrogen
7. Creatinine
8. Aspartate Transaminase (AST)
9. Alanine Transaminase (ALT)

Completion date
31/12/2006

Eligibility

Key inclusion criteria
1. Patients with type 2 diabetes under long-term insulin injection
2. Age between 40 and 86 years
3. Insulin dosage >10 units/24 h
4. Insulin injection duration >3 months
5. C-peptide in 24-hr urine >10 micrograms
6. Fasting CPR >0.5 ng/ml

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Not Specified

Sex
All

Total final enrolment
36

Key exclusion criteria
1. Positive for glutamine acid decarboxylase antibody
2. ALT and/or AST >3 times the upper limit of normal

3. Presently and/or in the past suffering from heart failure
4. Ejection fraction assessed by echocardiography <40%
5. Malignancy on active therapeutic regimen or without complete remission or cure
6. Concomitantly suffering from infection
7. Planning to have surgery
8. >50% positivity for insulin antibody
9. Diagnosis of type I diabetes
10. Pregnant or breast feeding
11. Under dialysis
12. Concomitantly using pioglitazone

Date of first enrolment
01/05/2005

Date of final enrolment
31/12/2006

Locations

Countries of recruitment
Japan

Study participating centre
793-1
Hokkaido
Japan
099-2102

Sponsor information

Organisation
Okhotsk-kai Hospital (Japan)

ROR
https://ror.org/0261c1d14

Funder(s)

Funder type
Hospital/treatment centre

Funder Name

Okhotsk-kai Hospital (Japan)

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		11/11/2008	29/10/2021	Yes	No