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Trial to evaluate effects of the intention to treat for insulin resistance (ITT-IR) to prevent cardiovascular events in early stages of diabetes

Submission date
01/04/2024

Recruitment status
No longer recruiting

Registration date
05/04/2024

Overall study status
Completed

Last Edited
08/04/2024

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

Background and study aims
To evaluate whether the intention to treat for insulin resistance (ITT-IR) can prevent cardiovascular events in diabetes patients with the early stages of treatment (early diabetes; life-style intervention/non-insulinotropic drugs/incretin drugs).

Who can participate?
Diabetes patients with the early stages of treatment (early-stage diabetes: life-style intervention /non-insulinotropic drugs/incretin drugs) at baseline, who continue to follow for more than six months at diabetes center of Wakayama Rosai Hospital.

What does the study involve?
To evaluate whether the intention to treat for insulin resistance (ITT-IR) can prevent cardiovascular events in the early-stage diabetes.

What are the possible benefits and risks of participating?
Self-monitoring determined a target may be useful for cognition of physical parameter and resultant acceptance of treatment on diet and prescription.
Following V with abdominal CT may motivate patients to increase ADL.
Preferential prescription of non-insulinotropic diabetes drugs [biguanide, α-glucosidase inhibitor, thiazolidine, or sodium glucose co-transporter 2 (SGLT2) inhibitor] and disuse of insulinotropic drugs (DPP4I, GN and SU), as far as possible, may affect the adherence of patient.
The prevalence of hypoglycemia and the progression of retinopathy may differ.
The following rate in G-I may decrease from the change of treatment policy.

Where is the study run from?
Wakayama Rosai Hospital (Japan)

When is the study starting and how long is it expected to run for?
April 2016 to June 2021

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
Dr Takashi Ohoshi, tks-oohoshi@wakayamah.johas.go.jp

Contact information

Type(s)
Public, Scientific, Principal investigator

Contact name
Dr Takashi Ohoshi

ORCID ID
https://orcid.org/0009-0007-3498-2419

Contact details
93-1Kinomoto
Wakayama
Japan
640-8505
+81 734513181
tks-oohoshi@wakayamah.johas.go.jp

Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Protocol serial number
IRS 123456

Study information

Scientific Title
Cluster randomized parallel controlled trial to evaluate effects of the intention to treat for insulin resistance (ITT-IR) to prevent cardiovascular events in early stages of diabetes

Acronym
ITT-IR trial

Study objectives
From the ACCORD and Steno-2 Study, it became clear that pushing glucose levels as low as possible in diabetic patients with a long duration of the condition could be harmful. It was evident that managing not just blood glucose but also other existing risk factors comprehensively was necessary to prevent cardiovascular complications. However, because of the need to address multiple risk factors in comprehensive therapy, the treatment focus became unclear. Thus, this study sought to address insulin resistance, the primary pathogenic feature of

diabetes, particularly in the early stages of type 2 and possibly slowly progressive type 1. We aimed to determine whether the intention to treat insulin resistance (ITT-IR) could effectively prevent cardiovascular events in the early stages of diabetes.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 26/08/2022, Ethics committee of Wakayama Rosai Hospital (93-1 Kinomoto, Wakayama city, 640-8505, Japan; +81 734513181; ohoshi03@yahoo.co.jp), ref: 22—06

Study design
Cluster randomized open parallel controlled single-centre trial

Primary study design
Interventional

Study type(s)
Prevention, Treatment, Safety, Efficacy

Health condition(s) or problem(s) studied
Early stages of diabetes

Interventions
Intervention group (G-I): The protocols of I [self-monitoring of steps, of body weight and of blood pressure (BP), following of visceral fat area (V) in abdominal obese patients, diet advise by dietitian, and preferential prescription of non-insulinotropic drugs] were recommended from baseline to 65 weeks (I-period). After I-period we continued to follow until week 272.

Control group (G-C): Conventional treatment for diabetes mellitus from baseline to 272 weeks.

Authors adopted cluster randomization from the complex intervention unable to mask. Of seven doctors in diabetes center, only one doctor treated patients according to “ITT-IR” policy. Researcher did not inform patients and other doctors on this policy in advance to reduce minimally influence on their mode of treatment. The ninety patients of ITT-IR (G-I) were randomly allocated and followed using intention-to-treat (ITT) analysis.

Intervention Type
Mixed

Primary outcome(s)
Measured using patient records at the end of study:
Percutaneous coronary intervention, carotid endarterectomy, carotid artery stenting, endovascular treatment, thromboendarterectomy, coronary artery bypass grafting, ablation, implantable cardioverter defibrillator, clipping for aneurysm of intracranial arteries, amputation from gangrene, non-fatal stroke, non-fatal myocardial infarction(MI), hemodialysis, frailty, dementia, hospitalization from heart failure, death from cardiovascular causes, death from renal failure, death from frailty)

Key secondary outcome(s))

Measured using patient records at the end of study:
Hospitalization from complications or comorbidities, death)

Completion date
30/06/2021

Eligibility

Key inclusion criteria
Diabetes patients visited outpatient clinic in Wakayama Rosai Hospital from April to June in 2016

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
16 years

Upper age limit
90 years

Sex
All

Total final enrolment
757

Key exclusion criteria
Cannot continue to visit our outpatient clinic

Date of first enrolment
05/04/2016

Date of final enrolment
30/06/2016

Locations

Countries of recruitment
Japan

Study participating centre

Diabetes centre, Wakayama Rosai Hospital
93-1 Kinomoto
Wakayama city
Japan
640-8505

Sponsor information

Organisation
Wakayama Rosai Hospital

ROR
https://ror.org/00awxvj03

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan
Raw data are available on reasonable request to the corresponding author. All data relevant to the study are included in publication data.
ohoshi03@yahoo.co.jp

IPD sharing plan summary
Available on request