# 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	Recruitment status	<ul><li>Prospectively registered</li></ul>
01/04/2024	No longer recruiting	☐ Protocol
Registration date	Overall study status	Statistical analysis plan
05/04/2024	Completed	Results
Last Edited	Condition category	Individual participant data
08/04/2024	Nutritional, Metabolic, Endocrine	<ul><li>Record updated in last year</li></ul>

# 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; lifestyle 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,  $\alpha$ -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

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# Additional identifiers

#### Clinical Trials Information System (CTIS)

Nil known

# ClinicalTrials.gov (NCT)

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

# Study outputs

Date created Date added Peer reviewed? Patient-facing? Output type **Details** Participant information sheet 11/11/2025 11/11/2025 No

Yes

Participant information sheet