

# Multicentre, randomised, double-blind, parallel-group, placebo-controlled clinical trial, comparing nateglinide versus placebo to assess the efficacy and tolerability of nateglinide in patients with type two diabetes mellitus

<b>Submission date</b> 31/10/2006	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 07/11/2006	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 16/10/2009	<b>Condition category</b> 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 Ramon Gomis

**Contact details**  
Endocrinology and Diabetes Unit  
Hospital Clinic i Universitari  
Institut d'Investigacions Biomediques August Pi i Sunyer (IDIBAPS)  
C/Villarroel, 170  
Barcelona  
Spain  
08036  
gomis@medicina.ub.es

## Additional identifiers

## Study information

Scientific Title

## **Study objectives**

Nateglinide is a new oral hypoglycemic agent that increases insulin secretion. In contrast to other oral hypoglycemic agents it mainly decreases postprandial hyperglycemia and it has this effect with lower risk for hypoglycemic events.

Postprandial hyperglycemia appears in the early stages with type two diabetes mellitus and we hypothesise that the use of nateglinide at these stages should improve glycemic control (in terms of HbA1c levels and postprandial hyperglycemia) without any significant increases of its adverse effects.

## **Ethics approval required**

Old ethics approval format

## **Ethics approval(s)**

The current study received Ethical Committees approval at all the participating sites: Hospital Virgen del Rocio, Hospital Infanta Elena, Hospital Reina Sofia, C.M. Teknon, Hospital Sant Joan, Hospital Universitario de Valme, Hospital Puerta del Mar, CAP Sils, Hospital Clínic i Universitari de Barcelona, Hospital de Sabadell, CAP El Remei, Hospital de La Merced, EAP Cervera, CS Torrero Este, Unidad de Calidad de Formación, Fundació Sarda Farriol, Hospital Esperit Sant, Hospital La Macarena, Clínica Corachán, CAP Cerdanya, CS Los Comuneros, Hospital San Vicente Raspeig, CS Petrel and CAP Centelles.

## **Study design**

Multicentre, double-blind, parallel-group, placebo-controlled, randomised trial comparing nateglinide (120 mg, three times daily) versus placebo after a follow-up period of 12 weeks.

## **Primary study design**

Interventional

## **Study type(s)**

Treatment

## **Health condition(s) or problem(s) studied**

Type two diabetes mellitus with more than five years of evolution

## **Interventions**

This study only compares Nateglinide (120 mg, three times daily) versus placebo. No other interventions were carried out nor compared.

## **Intervention Type**

Drug

## **Phase**

Not Specified

## **Drug/device/biological/vaccine name(s)**

Nateglinide

## **Primary outcome(s)**

Difference in HbA1c levels between the two study groups, at 12 weeks of follow-up

### **Key secondary outcome(s)**

At 12 weeks of follow-up:

1. Fasting plasma glucose
2. Incremental Areas Under the Curve for glucose (IAUC<sub>glucose</sub>) and C-Peptide (IAUC<sub>C-peptide</sub>) after a breakfast challenge test
3. Weight, heart rate and blood pressure
4. Haemoglobin, hematocrit and blood cell counts
5. Creatinine
6. ALT and AST levels
7. Fasting triglycerides
8. Total cholesterol
9. Homeostasis Model Assessment (HOMA)-%B (insulin secretion) and HOMA-%S (insulin sensitivity)

### **Completion date**

25/07/2003

## **Eligibility**

### **Key inclusion criteria**

Drug-naive 30 to 75 year old subjects with type two Diabetes Mellitus (DM) and less than five years of evolution, who met the following criteria:

1. Body Mass Index (BMI): 22 to 35 kg/m<sup>2</sup>
2. Fasting Plasma Glucose (FPG) less than 13.3 mmol/l
3. HbA1c: 6.5 to 8.5%
4. Not taking anti-hypertensive drugs

To be included, participants were in agreement neither to change their prior diet nor exercise activity during follow-up

### **Participant type(s)**

Patient

### **Healthy volunteers allowed**

No

### **Age group**

Not Specified

### **Sex**

All

### **Key exclusion criteria**

1. Type one diabetes mellitus
2. Pregnancy or childbearing females not using oral contraceptives
3. Drug-abuse
4. Severe psychiatric disorders
5. Treatment with oral corticosteroids, insulin or other oral hypoglycemic agents

6. Serum creatinine more than 160 mmol/L
7. Alanine Transaminase (ALT) and/or Aspartate Transaminase (AST) more than 2.0 x Upper Limit of Normal (ULN)
8. Thyroid dysfunction
9. Fasting triglycerides more than 7.0 mmol/L
10. Total cholesterol more than 9.1 mmol/L

**Date of first enrolment**

26/09/2001

**Date of final enrolment**

25/07/2003

## Locations

**Countries of recruitment**

Spain

**Study participating centre**

Endocrinology and Diabetes Unit

Barcelona

Spain

08036

## Sponsor information

**Organisation**

Novartis Pharma (Novartis Farmacéutica SA) (Spain)

**ROR**

<https://ror.org/042e6sa59>

## Funder(s)

**Funder type**

Industry

**Funder Name**

Novartis Pharma (Spain) (ref: CDJN608AES03)

**Funder Name**

Institute of Health Carlos III (Instituto de Salud Carlos III) (Spain) (ref: RGDM 03/212)

**Results and Publications**

**Individual participant data (IPD) sharing plan**

**IPD sharing plan summary**

Not provided at time of registration