

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

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

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Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N/A

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

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 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 measure

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

Secondary outcome measures

At 12 weeks of follow-up:

1. Fasting plasma glucose
2. Incremental Areas Under the Curve for glucose (IAUCglucose) and C-Peptide (IAUCC-peptide) 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)

Overall study start date

26/09/2001

Completion date

25/07/2003

Eligibility**Key inclusion criteria**

Drug-naïve 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/m²
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

Age group

Not Specified

Sex

Both

Target number of participants

At least 51 subjects in each study group

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)

Sponsor details

Gran Via de les Corts Catalanes, 764.

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gemma.gambus@pharma.novartis.com

Sponsor type

Industry

Website

<http://www.novartis.es/>

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**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