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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	Recruitment status	[ ] Prospectively registered
31/10/2006	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
07/11/2006	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
16/10/2009	Nutritional, Metabolic, Endocrine	[ ] 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

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 Cerdenya, 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-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^2
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.
Barcelona
Spain
08013
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