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**FILING DATE:** ***December 19, 2014***
**PATENT NUMBER:** ***9764003***
**ISSUE DATE:** ***September 19, 2017***

Certified by

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Under Secretary of Commerce
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| Notice of References Cited | Application/Control No. 14/409,493 | Applicant(s)/Patent Under Reexamination JENSEN ET AL. | |
|---|---|---|---|
| | Examiner KRISTINA M. HELLMAN | Art Unit 1675 | Page 1 of 2 |

**U.S. PATENT DOCUMENTS**

| * | | Document Number Country Code-Number-Kind Code | Date MM-YYYY | Name | CPC Classification | US Classification |
|---|---|---|---|---|---|---|
| | A | US- | | | | |
| | B | US- | | | | |
| | C | US- | | | | |
| | D | US- | | | | |
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*A copy of this reference is not being furnished with this Office action. (See MPEP § 707.05(a).)
Dates in MM-YYYY format are publication dates. Classifications may be US or foreign.

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| | W | |
| | X | |

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← History of this study ↑ Current version of this study

# View of NCT00696657 on 2011_03_25

**ClinicalTrials Identifier:** NCT00696657
**Updated:** 2011_03_25

## Descriptive Information

**Brief title** A Randomised Controlled Clinical Trial in Type 2 Diabetes Comparing Semaglutide to Placebo and Liraglutide

**Official title** Investigation of Safety and Efficacy of Five Doses of Semaglutide Versus Placebo and Open-label Liraglutide, as Add on Therapy, in Subjects Diagnosed With Type 2 Diabetes Currently Treated With Metformin or Controlled With Diet and Exercise A 12 Week Multi-centre, Multi National, Double-blind, Placebo-controlled, Randomised, Nine Armed Parallel Group, Dose Finding Trial

**Brief summary**

This trial was conducted in Europe,Asia and Africa.
Study participants were randomised evenly to treatment with semaglutide (0.1 mg QW - 1.6 mg QW, 6 treatment arms, placebo or liraglutide (1.2 mg QD, or 1.8 mg QD).Treatment allocation to semaglutide or placebo was double-blind, whereas liraglutide treatment was administered open-label.Primary efficacy parameter was HbA1c and the treatment duration was 12 weeks.

**Detailed description**

| | |
|---|---|
| **Phase** | Phase 2 |
| **Study type** | Interventional |
| **Study design** | Treatment |
| **Study design** | Randomized |
| **Study design** | Double Blind (Subject, Investigator) |
| **Study design** | Placebo Control |
| **Study design** | Parallel Assignment |
| **Study design** | Safety/Efficacy Study |
| **Primary outcome** | Measure: HbA1c<br>Time Frame: after 12 weeks of treatment<br>Safety Issue? No |
| **Secondary outcome** | Measure: Percentage of subjects with an adverse events<br>Time Frame: after 12 weeks of treatment<br>Safety Issue? No |
| **Secondary outcome** | Measure: Percentage of subjects with hypoglycaemic episode<br>Time Frame: after 12 weeks of treatment<br>Safety Issue? No |
| **Secondary outcome** | Measure: Change from baseline in ECG |

| | |
|---|---|
| | Time Frame: week 0, week 12<br>Safety Issue? No |
| **Secondary outcome** | Measure: Change from baseline in vital signs (Pulse)<br>Time Frame: week 0, week 12<br>Safety Issue? No |
| **Secondary outcome** | Measure: Change from baseline in vital signs (blood pressure)<br>Time Frame: week 0, week 12<br>Safety Issue? No |
| **Secondary outcome** | Measure: Change from baseline in standard safety laboratory parameters (haematology)<br>Time Frame: week 0, week 12<br>Safety Issue? No |
| **Secondary outcome** | Measure: Change from baseline in standard safety laboratory parameters ( biochemistry)<br>Time Frame: week 0, week 12<br>Safety Issue? No |
| **Secondary outcome** | Measure: Change from baseline in standard safety laboratory parameters (urinalysis)<br>Time Frame: week 0, week 12<br>Safety Issue? No |
| **Secondary outcome** | Measure: Change from baseline in calcitonin<br>Time Frame: week 0, week 12<br>Safety Issue? No |
| **Secondary outcome** | Measure: Percentage of subjects developing anti-semaglutide antibodies<br>Time Frame: after 12 weeks of treatment<br>Safety Issue? No |
| **Enrollment** | 415 (Actual) |
| **Condition** | Diabetes Mellitus, Type 2 |
| **Arm/Group** | Arm Label: A Experimental |
| **Arm/Group** | Arm Label: B Experimental |
| **Arm/Group** | Arm Label: C Experimental |
| **Arm/Group** | Arm Label: D Experimental |
| **Arm/Group** | Arm Label: E Experimental |
| **Arm/Group** | Arm Label: F Experimental |
| **Arm/Group** | Arm Label: G1 Placebo Comparator |
| **Arm/Group** | Arm Label: G2 Placebo Comparator |
| **Arm/Group** | Arm Label: G3 Placebo Comparator |
| **Arm/Group** | Arm Label: G4 Placebo Comparator |

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