Protocol Registration Receipt
05/29/2014

Grantor: CDER IND/IDE Number: 65,177 Serial Number:

A Study to Determine the Safety and Efficacy of Albiglutide in Subjects With Type 2 Diabetes

This study has been completed.

Sponsor:	GlaxoSmithKline
Collaborators:	
Information provided by (Responsible Party):	GlaxoSmithKline
ClinicalTrials.gov Identifier:	NCT00839527

Purpose

The purpose of this study is to determine the safety and efficacy of albiglutide in subjects with type 2 diabetes

Condition	Intervention	Phase
Diabetes Mellitus, Type 2	Drug: placebo to match albiglutide Biological/Vaccine: albiglutide Drug: metformin	Phase 3

Condition	Intervention	Phase
	Drug: glimepiride Drug: pioglitazone Drug: placebo to match pioglitazone	

Study Type: Interventional

Study Design: Treatment, Parallel Assignment, Double Blind (Subject, Investigator), Randomized, Safety/Efficacy Study

Official Title: A Randomized, Double-blind, Placebo and Active-Controlled, Parallel-group, Multicenter Study to Determine the Efficacy and Safety of Albiglutide Administered in Combination With Metformin and Glimepiride Compared With Metformin Plus Glimepiride and Placebo and With Metformin Plus Glimepiride and Pioglitazone in Subjects With Type 2 Diabetes Mellitus

Further study details as provided by GlaxoSmithKline:

Primary Outcome Measure:

- Change From Baseline (BL) in Glycosylated Hemoglobin (HbA1c) at Week 52 [Time Frame: Baseline and Week 52] [Designated as safety issue: No]
  HbA1c is a form of hemoglobin that is measured primarily to identify the average plasma glucose concentration over a 2- to 3-month period. The BL HbA1c value is defined as the last non-missing value before the start of treatment. Change from BL was calculated as the value at Week 52 minus the value at BL. Based on analysis of covariance (ANCOVA): change = treatment + BL HbA1c + prior myocardial infarction history + age category + region. The last observation carried forward (LOCF) method was used to impute missing post-BL HbA1c values; the last non-missing post-BL on-treatment measurement was used to impute the missing measurement. HbA1c values obtained after hyperglycemic rescue were treated as missing and were replaced with pre-rescue values. Nine par. with post-BL values obtained >14 days after the last dose or after hyperglycemic rescue were included in the analysis population but were not analyzed for this endpoint.

Secondary Outcome Measures:

- Change From Baseline in HbA1c at Week 104 and Week 156 [Time Frame: Baseline, Week 104, and Week 156] [Designated as safety issue: No]
  HbA1c is a form of hemoglobin that is measured primarily to identify the average plasma glucose concentration over a 2- to 3-month period. The Baseline HbA1c value is defined as the last non-missing value before the start of treatment. Change from Baseline was calculated as the post-Baseline value minus the Baseline value. This analysis used observed HbA1c values, excluding those obtained after hyperglycemia rescue; no missing data imputation was performed.
- Change From Baseline in Fasting Plasma Glucose (FPG) at Week 52 [Time Frame: Baseline and Week 52] [Designated as safety issue: No]
  The FPG test measures blood sugar levels after the participant has not eaten (fasted) for 12 to 14 hours. The Baseline FPG value is the last non-missing value before the start of treatment. The LOCF method was used to impute missing post-Baseline FPG values. FPG values obtained after hyperglycemia rescue were treated as missing and replaced with pre-rescue values. Change from Baseline was calculated as the post-Baseline value minus the Baseline value. Based on ANCOVA: change = treatment + Baseline FPG + Baseline HbA1c category + prior myocardial infarction history + age category + region.

- Change From Baseline in FPG at Week 104 and Week 156 [Time Frame: Baseline, Week 104, and Week 156] [Designated as safety issue: No]

  The FPG test measures blood sugar levels after the participant has not eaten (fasted) for 12 to 14 hours. The Baseline FPG value is the last non-missing value before the start of treatment. Change from Baseline was calculated as the post-Baseline value minus the Baseline value. This analysis used observed FPG values excluding those obtained after hyperglycemia rescue; no missing data imputation was performed.
- Time to Hyperglycemia Rescue [Time Frame: From the start of study medication until the end of the treatment (up to Week 156)] [Designated as safety issue: No]

  Participants who experienced persistent hyperglycemia (high blood glucose) could have qualified for hyperglycemia rescue. The conditions for hyperglycemia rescue were as follows: FPG >=280 milligrams/deciliter (mg/dL) between >=Week 2 and <Week 4; FPG >=250 mg/dL between >=Week 4 and <Week 12; HbA1c >=8.5% and a <=0.5% reduction from Baseline between >=Week 12 and <Week 24; HbA1c >=8.5% between >=Week 24 and <Week 48; HbA1c >=8.0% between >= Week 48 and <Week 156. Participants could have been rescued at any time on or after Week 2. Time to hyperglycemia rescue is defined as the time between the date of the first dose of study medication and the date of hyperglycemia rescue plus 1 day, or the time between the date of the first dose of study medication and the date of the last visit during the active treatment period plus 1 day for participants not requiring rescue. This time was divided by 7 to express the result in weeks.
- Number of Participants Who Achieved Clinically Meaningful HbA1c Response Levels of <6.5%, <7%, and <7.5% at Week 52 [Time Frame: Week 52] [Designated as safety issue: No]

  The number of participants who acheieved the HbA1c treatment goal (i.e., HbA1c response levels of <6.5%, <7%, and <7.5% at Week 52) was assessed. Values were carried forward for participants who were rescued or discontinued from active treatment before Week 52.
- Number of Participants Who Achieved Clinically Meaningful HbA1c Response Levels of <6.5%, <7%, and <7.5% at Week 156 [Time Frame: Week 156] [Designated as safety issue: No]

  The number of participants who acheieved the HbA1c treatment goal (i.e., HbA1c response levels of <6.5%, <7%, and <7.5% at Week 156) was assessed.
- Change From Baseline in Body Weight at Week 52 [Time Frame: Baseline and Week 52] [Designated as safety issue: No]

  The Baseline value is the last non-missing value before the start of treatment. Change from Baseline was calculated as the post-Baseline weight minus the Baseline weight. The LOCF method was used to impute missing post-Baseline weight values. Weight values obtained after hyperglycemia rescue were treated as missing and replaced with pre-rescue values. Based on ANCOVA: change = treatment + Baseline weight + Baseline HbA1c category + prior myocardial infarction history + age category + region.
- Change From Baseline in Body Weight at Week 104 and Week 156 [Time Frame: Baseline, Week 104, and Week 156] [Designated as safety issue: No]

  The Baseline value is the last non-missing value before the start of treatment. Change from Baseline was calculated as the post-Baseline weight minus the Baseline weight. This analysis used observed body weight values excluding those obtained after hyperglycemia rescue; no missing data imputation was performed.

Enrollment: 685
Study Start Date: February 2009
Study Completion Date: March 2013
Primary Completion Date: December 2010

Arms	Assigned Interventions
Active Comparator: metformin + glimepiride + pioglitazone + albiglutide placebo Metformin + glimepiride + pioglitazone + matching albiglutide placebo	Drug: placebo to match albiglutide albiglutide matching placebo weekly subcutaneous injection Drug: metformin metformin Drug: glimepiride glimepiride Drug: pioglitazone pioglitazone
Experimental: metformin + glimepiride + pioglitazone placebo + albiglutide Metformin + open-label glimepiride + pioglitazone matching placebo + albiglutide	Biological/Vaccine: albiglutide albiglutide weekly subcutaneous injection Drug: metformin metformin Drug: glimepiride glimepiride Drug: placebo to match pioglitazone pioglitazone matching placebo
Active Comparator: met + glimepiride + pioglitazone placebo + albiglutide placebo metformin + open-label glimepiride + pioglitazone placebo + albiglutide placebo	Drug: placebo to match albiglutide albiglutide matching placebo weekly subcutaneous injection Drug: metformin metformin Drug: glimepiride glimepiride Drug: placebo to match pioglitazone pioglitazone matching placebo

Eligibility

Ages Eligible for Study: 18 Years and older
Genders Eligible for Study: Both

Inclusion Criteria:

- type 2 diabetes
- BMI 20-45kg/m2 inclusive

Exclusion Criteria:

- females who are pregnant, lactating, or less than 6 weeks post-partum
- current symptomatic heart failure (NYHA Class II-IV)

Contacts and Locations

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Dallas, Texas, United States, 75235
GSK Investigational Site
Deer Park, Texas, United States, 77536
GSK Investigational Site
El Paso, Texas, United States, 79925
GSK Investigational Site
Fort Worth, Texas, United States, 76135
GSK Investigational Site
Fort Worth, Texas, United States, 76104
GSK Investigational Site
Fort Worth, Texas, United States, 76104
GSK Investigational Site
Houston, Texas, United States, 77030
GSK Investigational Site
Houston, Texas, United States, 77058
GSK Investigational Site
Houston, Texas, United States, 77074
GSK Investigational Site
Houston, Texas, United States, 77070
GSK Investigational Site
Houston, Texas, United States, 77055
GSK Investigational Site
Houston, Texas, United States, 77034
GSK Investigational Site

Houston, Texas, United States, 77036

GSK Investigational Site

Houston, Texas, United States, 77024

GSK Investigational Site

Houston, Texas, United States, 77030

GSK Investigational Site

Houston, Texas, United States, 77074

GSK Investigational Site

Houston, Texas, United States, 77036

GSK Investigational Site

Houston, Texas, United States, 77024

GSK Investigational Site

Houston, Texas, United States, 77030

GSK Investigational Site

Hurst, Texas, United States, 76054

GSK Investigational Site

Katy, Texas, United States, 77450

GSK Investigational Site

Katy, Texas, United States, 77450

GSK Investigational Site

Lake Jackson, Texas, United States, 77566

GSK Investigational Site

Lewisville, Texas, United States, 75067

GSK Investigational Site

Midland, Texas, United States, 79707

GSK Investigational Site

North Richland Hills, Texas, United States, 76180

GSK Investigational Site

Odessa, Texas, United States, 79761

GSK Investigational Site

San Antonio, Texas, United States, 78229

GSK Investigational Site

San Antonio, Texas, United States, 78218

GSK Investigational Site

San Antonio, Texas, United States, 78229

GSK Investigational Site
San Antonio, Texas, United States, 78258
GSK Investigational Site
San Antonio, Texas, United States, 78217
GSK Investigational Site
San Antonio, Texas, United States, 78229
GSK Investigational Site
San Antonio, Texas, United States, 78224
GSK Investigational Site
San Antonio, Texas, United States, 78258
GSK Investigational Site
San Antonio, Texas, United States, 78229
GSK Investigational Site
San Antonio, Texas, United States, 78215
GSK Investigational Site
Schertz, Texas, United States, 78154
GSK Investigational Site
Sugar Land, Texas, United States, 77479
GSK Investigational Site
Sugarland, Texas, United States, 77479
GSK Investigational Site
Temple, Texas, United States, 76508

United States, Utah

GSK Investigational Site
Orem, Utah, United States, 84058
GSK Investigational Site
Salt Lake City, Utah, United States, 84107
GSK Investigational Site
Salt Lake City, Utah, United States, 84102
GSK Investigational Site
West Jordan, Utah, United States, 84088
GSK Investigational Site
West Valley City, Utah, United States, 84120
GSK Investigational Site
West Valley City, Utah, United States, 84120

United States, Vermont

GSK Investigational Site

South Burlington, Vermont, United States, 05403

United States, Virginia

GSK Investigational Site

Burke, Virginia, United States, 22015

GSK Investigational Site

Hampton, Virginia, United States, 23666

GSK Investigational Site

Manassas, Virginia, United States, 20110

GSK Investigational Site

Norfolk, Virginia, United States, 23502

GSK Investigational Site

Richmond, Virginia, United States, 23294

GSK Investigational Site

Suffolk, Virginia, United States

GSK Investigational Site

Virgina Beach, Virginia, United States, 23455

GSK Investigational Site

Weber City, Virginia, United States, 24290

United States, Washington

GSK Investigational Site

Federal Way, Washington, United States, 98003

GSK Investigational Site

Renton, Washington, United States, 98057

GSK Investigational Site

Richland, Washington, United States, 99352

GSK Investigational Site

Selah, Washington, United States, 98942

GSK Investigational Site

Spokane, Washington, United States, 99216

GSK Investigational Site

Spokane, Washington, United States, 99208

GSK Investigational Site

Tacoma, Washington, United States, 98405

United States, West Virginia

GSK Investigational Site

Lewisburg, West Virginia, United States, 24901

United States, Wisconsin

GSK Investigational Site

Milwaukee, Wisconsin, United States, 53226

Germany

GSK Investigational Site

Villingen-Schwenningen, Baden-Wuerttemberg, Germany, 78054

GSK Investigational Site

Kuenzing, Bayern, Germany, 94550

GSK Investigational Site

Berlin, Berlin, Germany, 10115

GSK Investigational Site

Kelkheim, Hessen, Germany, 65779

GSK Investigational Site

Rotenburg, Hessen, Germany, 36199

GSK Investigational Site

Bad Lauterberg, Niedersachsen, Germany, 37431

GSK Investigational Site

Mainz, Rheinland-Pfalz, Germany, 55116

Hong Kong

GSK Investigational Site

Chaiwan, Hong Kong

GSK Investigational Site

Kwun Tong, Kowloon, Hong Kong

GSK Investigational Site

Shatin, Hong Kong

GSK Investigational Site

Tai Po,, Hong Kong

India

GSK Investigational Site

Aurangabad, India, 431001

GSK Investigational Site

Bangalore, India, 560043

GSK Investigational Site

Chennai, India, 600086

GSK Investigational Site

Pune, India, 411 011

GSK Investigational Site

Pune, India, 411011

Peru

GSK Investigational Site

Ica, Ica, Peru, 11

GSK Investigational Site

Callao, Lima, Peru, Callao 2

GSK Investigational Site

Lima, Lima, Peru, 01

GSK Investigational Site

Lima, Lima, Peru, 01

GSK Investigational Site

Lima, Lima, Peru, Lima 1

Philippines

GSK Investigational Site

Cebu City, Philippines, 6000

GSK Investigational Site

Marikina City, Philippines, 1810

GSK Investigational Site

Quezon City, Philippines, 1101

GSK Investigational Site

Quezon City, Philippines, 1102

GSK Investigational Site

San Juan, Philippines, 1500

GSK Investigational Site

Taytay Rizal, Philippines, 1920

Russian Federation

GSK Investigational Site

Smolensk, Russian Federation, 214 019

GSK Investigational Site

Yaroslavl, Russian Federation, 150062

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GSK Investigational Site

Alzira/Valencia, Spain, 46600

GSK Investigational Site

Barcelona, Spain, 08022

GSK Investigational Site

Madrid, Spain, 28034

GSK Investigational Site

Palma de Mallorca, Spain, 07010

GSK Investigational Site

Sevilla, Spain, 41003

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GSK Investigational Site

Glasgow, United Kingdom, G45 9AW

GSK Investigational Site

London, United Kingdom, SE1 9NH

GSK Investigational Site

Blackpool, Lancashire, United Kingdom, FY4 3AD

GSK Investigational Site

Coventry, West Midlands, United Kingdom, CV2 2DX

Investigators

Study Director:	GSK Clinical Trials	GlaxoSmithKline

More Information

Responsible Party:	GlaxoSmithKline
Study ID Numbers:	112757
Health Authority:	United States: Food and Drug Administration

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Study Results

Participant Flow

Pre-Assignment Details

Participants (par.) who met eligibility criteria and completed a 6- to 8-week Run-in/Stabilization Period were then randomized to a 156-week Treatment Period, followed by 8 weeks of post-treatment follow-up. A total of 992 par. were screened; 685 par. were randomized, and 663 par. received >=1 treatment dose.

Reporting Groups

	Description
Placebo + Metformin + Glimepiride	Participants received albiglutide matching placebo as a subcutaneous injection weekly via a fully disposable pen injector system with open-label glimepiride (4 milligrams [mg] daily orally) with metformin (>=1500 mg daily orally). Participants did not receive investigational product during the Follow-up Period.
Pioglitazone + Metformin + Glimepiride	Participants received pioglitazone (30 mg daily orally; with treatment-masked uptitration if needed to 45 mg) and albiglutide-matching placebo weekly as a subcutaneous injection via a fully disposable pen injector system with open-label glimepiride (4 mg daily orally) with metformin (>=1500 mg daily orally). Participants did not receive investigational product during the Follow-up Period.
Albiglutide + Metformin + Glimepiride	Participants received pioglitazone-matching placebo daily orally and albiglutide (30 mg weekly; treatment-masked uptitration if needed to 50 mg weekly) as a subcutaneous injection via a fully disposable pen injector system with open-label glimepiride (4 mg daily orally) with metformin (>=1500 mg daily orally). Participants did not receive investigational product during the Follow-up Period.

Treatment Period (TP) (156 Weeks)

	Placebo + Metformin + Glimepiride	Pioglitazone + Metformin + Glimepiride	Albiglutide + Metformin + Glimepiride
Started	115	277	271
Completed	55	159	152
Not Completed	60	118	119
Adverse Event	11	29	22
Protocol Violation	4	7	1
Noncompliance	5	6	16
Lost to Follow-up	3	12	7
Withdrawal by Subject	32	46	64
Physician Decision	1	6	1
Termination of Site by Sponsor	3	8	5
Missing	0	1	0
Persistant Elevated HbA1c Results	0	0	1
Pregnancy	0	1	1
Site Closed	1	2	0
Sponsor Decision on Blinding	0	0	1

Follow-up Period (FUP) (8 Weeks)

	Placebo + Metformin + Glimepiride	Pioglitazone + Metformin + Glimepiride	Albiglutide + Metformin + Glimepiride
Started	114 [1]	273 [2]	266 [3]
Completed	86	217	204
Not Completed	28	56	62
Adverse Event	1	2	1
Noncompliance	1	0	5
Lost to Follow-up	8	20	29
Withdrawal by Subject	12	21	19
Physician Decision	0	0	1
Termination of Study by Sponsor	3	10	5
Informed Consent Recalled by Participant	1	0	0
Investigator Closed Study at Site	1	0	0
Site Closed	0	1	0
Site Closing and Withdrew Consent	1	0	1
Unable to Complete Follow-up	0	1	0
Missing Follow-up Status	0	1	1

[1] Par. withdrawing from the TP could enter the FUP. One par. did not participate in the FUP.

[2] Par. withdrawing from the TP could enter the FUP. Four par. did not participate in the FUP.

[3] Par. withdrawing from the TP could enter the FUP. Five par. did not participate in the FUP.

Baseline Characteristics

Reporting Groups

	Description
Placebo + Metformin + Glimepiride	Participants received albiglutide matching placebo as a subcutaneous injection weekly via a fully disposable pen injector system with open-label glimepiride (4 milligrams [mg] daily orally) with metformin (>=1500 mg daily orally). Participants did not receive investigational product during the Follow-up Period.
Pioglitazone + Metformin + Glimepiride	Participants received pioglitazone (30 mg daily orally; with treatment-masked uptitration if needed to 45 mg) and albiglutide-matching placebo weekly as a subcutaneous injection via a fully disposable pen injector system with open-label glimepiride (4 mg daily orally) with metformin (>=1500 mg daily orally). Participants did not receive investigational product during the Follow-up Period.
Albiglutide + Metformin + Glimepiride	Participants received pioglitazone-matching placebo daily orally and albiglutide (30 mg weekly; treatment-masked uptitration if needed to 50 mg weekly) as a subcutaneous injection via a fully disposable pen injector system with open-label glimepiride (4 mg daily orally) with metformin (>=1500 mg daily orally). Participants did not receive investigational product during the Follow-up Period.

Baseline Measures

	Placebo + Metformin + Glimepiride	Pioglitazone + Metformin + Glimepiride	Albiglutide + Metformin + Glimepiride	Total
Number of Participants	115	277	271	663
Age, Continuous	55.7 (9.59)	55.7 (9.39)	54.5 (9.47)	55.2 (9.46)

	Placebo + Metformin + Glimepiride	Pioglitazone + Metformin + Glimepiride	Albiglutide + Metformin + Glimepiride	Total
[units: Years] Mean (Standard Deviation)				
Gender, Male/Female [units: Participants]				
Female	45	129	136	310
Male	70	148	135	353
Race/Ethnicity, Customized [units: Participants]				
African American/African Heritage	10	24	34	68
American Indian or Alaskan Native	9	10	22	41
Asian - Central/South Asian Heritage	6	6	8	20
Asian - East Asian Heritage	2	8	12	22
Asian - Japanese Heritage	0	1	2	3
Asian - South East Asian Heritage	7	24	14	45
Native Hawaiian or Other Pacific Islander	1	1	0	2
White - Arabic/North African Heritage	1	2	2	5
White - White/Caucasian/European Heritage	79	201	176	456

	Placebo + Metformin + Glimepiride	Pioglitazone + Metformin + Glimepiride	Albiglutide + Metformin + Glimepiride	Total
Mexican American	0	0	1	1

Outcome Measures

1. Primary Outcome Measure:

Measure Title	Change From Baseline (BL) in Glycosylated Hemoglobin (HbA1c) at Week 52
Measure Description	HbA1c is a form of hemoglobin that is measured primarily to identify the average plasma glucose concentration over a 2- to 3-month period. The BL HbA1c value is defined as the last non-missing value before the start of treatment. Change from BL was calculated as the value at Week 52 minus the value at BL. Based on analysis of covariance (ANCOVA): change = treatment + BL HbA1c + prior myocardial infarction history + age category + region. The last observation carried forward (LOCF) method was used to impute missing post-BL HbA1c values; the last non-missing post-BL on-treatment measurement was used to impute the missing measurement. HbA1c values obtained after hyperglycemic rescue were treated as missing and were replaced with pre-rescue values. Nine par. with post-BL values obtained >14 days after the last dose or after hyperglycemic rescue were included in the analysis population but were not analyzed for this endpoint.
Time Frame	Baseline and Week 52
Safety Issue?	No

Analysis Population Description

Intent-to-Treat (ITT) Population with LOCF: all randomized par. who received >=1 dose of study medication and who had a BL assessment and >=1

post-BL assessment of HbA1c. Only par. with a value at BL and at the specified visit were analyzed. Values were carried forward for par. who were rescued or discontinued from active treatment before Week 52.

Reporting Groups

	Description
Placebo + Metformin + Glimepiride	Participants received albiglutide matching placebo as a subcutaneous injection weekly via a fully disposable pen injector system with open-label glimepiride (4 milligrams [mg] daily orally) with metformin (>=1500 mg daily orally). Participants did not receive investigational product during the Follow-up Period.
Pioglitazone + Metformin + Glimepiride	Participants received pioglitazone (30 mg daily orally; with treatment-masked uptitration if needed to 45 mg) and albiglutide-matching placebo weekly as a subcutaneous injection via a fully disposable pen injector system with open-label glimepiride (4 mg daily orally) with metformin (>=1500 mg daily orally). Participants did not receive investigational product during the Follow-up Period.
Albiglutide + Metformin + Glimepiride	Participants received pioglitazone-matching placebo daily orally and albiglutide (30 mg weekly; treatment-masked uptitration if needed to 50 mg weekly) as a subcutaneous injection via a fully disposable pen injector system with open-label glimepiride (4 mg daily orally) with metformin (>=1500 mg daily orally). Participants did not receive investigational product during the Follow-up Period.

Measured Values

	Placebo + Metformin + Glimepiride	Pioglitazone + Metformin + Glimepiride	Albiglutide + Metformin + Glimepiride
Number of Participants Analyzed	115	268	265
Change From Baseline (BL) in Glycosylated Hemoglobin (HbA1c) at	0.33 (0.083)	-0.80 (0.055)	-0.55 (0.055)

	Placebo + Metformin + Glimepiride	Pioglitazone + Metformin + Glimepiride	Albiglutide + Metformin + Glimepiride
Week 52 [units: Percentage of HbA1c in the blood] Least Squares Mean (Standard Error)			

Statistical Analysis 1 for Change From Baseline (BL) in Glycosylated Hemoglobin (HbA1c) at Week 52

Groups	Placebo + Metformin + Glimepiride, Albiglutide + Metformin + Glimepiride
Method	ANCOVA
P-Value	<0.0001
Mean Difference (Net)	-0.87
95% Confidence Interval	-1.07 to -0.68

Additional details about the analysis, such as null hypothesis and power calculation:

[Not specified.]

Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:

[Not specified.]

Other relevant information, such as adjustments or degrees of freedom:

[Not specified.]

Statistical Analysis 2 for Change From Baseline (BL) in Glycosylated Hemoglobin (HbA1c) at Week 52

Groups	Pioglitazone + Metformin + Glimepiride, Albiglutide + Metformin + Glimepiride
Non-Inferiority/Equivalence Test	Yes
Method	t-test, 1 sided
P-Value	0.2685

Mean Difference (Net)	0.25
95% Confidence Interval	0.10 to 0.40

Additional details about the analysis, such as null hypothesis and power calculation:

[Not specified.]

The p-value is from a one-sided t-test testing at the 0.025 level of significance whether or not the difference of least square means (albiglutide - pioglitazone) is less than or equal to the pre-specified non-inferiority margin of 0.3%.

Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:

[Not specified.]

Other relevant information, such as adjustments or degrees of freedom:

[Not specified.]

2. Secondary Outcome Measure:

Measure Title	Change From Baseline in HbA1c at Week 104 and Week 156
Measure Description	HbA1c is a form of hemoglobin that is measured primarily to identify the average plasma glucose concentration over a 2- to 3-month period. The Baseline HbA1c value is defined as the last non-missing value before the start of treatment. Change from Baseline was calculated as the post-Baseline value minus the Baseline value. This analysis used observed HbA1c values, excluding those obtained after hyperglycemia rescue; no missing data imputation was performed.
Time Frame	Baseline, Week 104, and Week 156
Safety Issue?	No

Analysis Population Description

ITT Population with observed values. Only those participants with a value at Baseline and at the specified visit were analyzed (represented by n=X, X, X

in the category titles).

Reporting Groups

	Description
Placebo + Metformin + Glimepiride	Participants received albiglutide matching placebo as a subcutaneous injection weekly via a fully disposable pen injector system with open-label glimepiride (4 milligrams [mg] daily orally) with metformin (>=1500 mg daily orally). Participants did not receive investigational product during the Follow-up Period.
Pioglitazone + Metformin + Glimepiride	Participants received pioglitazone (30 mg daily orally; with treatment-masked uptitration if needed to 45 mg) and albiglutide-matching placebo weekly as a subcutaneous injection via a fully disposable pen injector system with open-label glimepiride (4 mg daily orally) with metformin (>=1500 mg daily orally). Participants did not receive investigational product during the Follow-up Period.
Albiglutide + Metformin + Glimepiride	Participants received pioglitazone-matching placebo daily orally and albiglutide (30 mg weekly; treatment-masked uptitration if needed to 50 mg weekly) as a subcutaneous injection via a fully disposable pen injector system with open-label glimepiride (4 mg daily orally) with metformin (>=1500 mg daily orally). Participants did not receive investigational product during the Follow-up Period.

Measured Values

	Placebo + Metformin + Glimepiride	Pioglitazone + Metformin + Glimepiride	Albiglutide + Metformin + Glimepiride
Number of Participants Analyzed	12	130	104
Change From Baseline in HbA1c at Week 104 and Week 156 [units: Percentage of HbA1c in the blood] Mean (Standard Deviation)			

	Placebo + Metformin + Glimepiride	Pioglitazone + Metformin + Glimepiride	Albiglutide + Metformin + Glimepiride
Week 104, n=12, 130, 104	-0.32 (0.552)	-1.09 (1.119)	-0.76 (1.009)
Week 156, n=9, 89, 71	-0.10 (0.923)	-0.97 (1.063)	-0.46 (1.113)

3. Secondary Outcome Measure:

Measure Title	Change From Baseline in Fasting Plasma Glucose (FPG) at Week 52
Measure Description	The FPG test measures blood sugar levels after the participant has not eaten (fasted) for 12 to 14 hours. The Baseline FPG value is the last non-missing value before the start of treatment. The LOCF method was used to impute missing post-Baseline FPG values. FPG values obtained after hyperglycemia rescue were treated as missing and replaced with pre-rescue values. Change from Baseline was calculated as the post-Baseline value minus the Baseline value. Based on ANCOVA: change = treatment + Baseline FPG + Baseline HbA1c category + prior myocardial infarction history + age category + region.
Time Frame	Baseline and Week 52
Safety Issue?	No

Analysis Population Description

Intent-to-Treat (ITT) Population with LOCF. Only those participants with a value at Baseline and at the specified visit were analyzed. Values were carried forward for participants who were rescued or discontinued from active treatment before Week 52.

Reporting Groups

	Description
Placebo + Metformin +	Participants received albiglutide matching placebo as a subcutaneous

	Description
Glimepiride	injection weekly via a fully disposable pen injector system with open-label glimepiride (4 milligrams [mg] daily orally) with metformin (>=1500 mg daily orally). Participants did not receive investigational product during the Follow-up Period.
Pioglitazone + Metformin + Glimepiride	Participants received pioglitazone (30 mg daily orally; with treatment-masked uptitration if needed to 45 mg) and albiglutide-matching placebo weekly as a subcutaneous injection via a fully disposable pen injector system with open-label glimepiride (4 mg daily orally) with metformin (>=1500 mg daily orally). Participants did not receive investigational product during the Follow-up Period.
Albiglutide + Metformin + Glimepiride	Participants received pioglitazone-matching placebo daily orally and albiglutide (30 mg weekly; treatment-masked uptitration if needed to 50 mg weekly) as a subcutaneous injection via a fully disposable pen injector system with open-label glimepiride (4 mg daily orally) with metformin (>=1500 mg daily orally). Participants did not receive investigational product during the Follow-up Period.

Measured Values

	Placebo + Metformin + Glimepiride	Pioglitazone + Metformin + Glimepiride	Albiglutide + Metformin + Glimepiride
Number of Participants Analyzed	115	272	268
Change From Baseline in Fasting Plasma Glucose (FPG) at Week 52 [units: Millimoles per liter (mmol/L)] Least Squares Mean (Standard Error)	0.64 (0.243)	-1.74 (0.158)	-0.69 (0.159)

4. Secondary Outcome Measure:

Measure Title	Change From Baseline in FPG at Week 104 and Week 156
Measure Description	The FPG test measures blood sugar levels after the participant has not eaten (fasted) for 12 to 14 hours. The Baseline FPG value is the last non-missing value before the start of treatment. Change from Baseline was calculated as the post-Baseline value minus the Baseline value. This analysis used observed FPG values excluding those obtained after hyperglycemia rescue; no missing data imputation was performed.
Time Frame	Baseline, Week 104, and Week 156
Safety Issue?	No

Analysis Population Description

ITT Population with observed values. Only those participants with a value at Baseline and at the specified visit were analyzed (represented by n=X, X, X in the category titles).

Reporting Groups

	Description
Placebo + Metformin + Glimepiride	Participants received albiglutide matching placebo as a subcutaneous injection weekly via a fully disposable pen injector system with open-label glimepiride (4 milligrams [mg] daily orally) with metformin (>=1500 mg daily orally). Participants did not receive investigational product during the Follow-up Period.
Pioglitazone + Metformin + Glimepiride	Participants received pioglitazone (30 mg daily orally; with treatment-masked uptitration if needed to 45 mg) and albiglutide-matching placebo weekly as a subcutaneous injection via a fully disposable pen injector system with open-label glimepiride (4 mg daily orally) with metformin (>=1500 mg daily orally). Participants did not receive investigational product during the Follow-up Period.
Albiglutide + Metformin + Glimepiride	Participants received pioglitazone-matching placebo daily orally and albiglutide (30 mg weekly; treatment-masked uptitration if needed to 50

	Description
	mg weekly) as a subcutaneous injection via a fully disposable pen injector system with open-label glimepiride (4 mg daily orally) with metformin (>=1500 mg daily orally). Participants did not receive investigational product during the Follow-up Period.

Measured Values

	Placebo + Metformin + Glimepiride	Pioglitazone + Metformin + Glimepiride	Albiglutide + Metformin + Glimepiride
Number of Participants Analyzed	12	128	103
Change From Baseline in FPG at Week 104 and Week 156 [units: Millimoles per liter (mmol/L)] Mean (Standard Deviation)			
Week 104, n=12, 128, 103	0.43 (3.346)	-1.98 (3.471)	-0.99 (3.083)
Week 156, n=9, 88, 71	-0.50 (4.093)	-1.94 (3.127)	-0.88 (2.652)

5. Secondary Outcome Measure:

Measure Title	Time to Hyperglycemia Rescue
Measure Description	Participants who experienced persistent hyperglycemia (high blood glucose) could have qualified for hyperglycemia rescue. The conditions for hyperglycemia rescue were as follows: FPG >=280 milligrams/deciliter (mg/dL) between >=Week 2 and <Week 4; FPG >=250 mg/dL between >=Week 4 and <Week 12; HbA1c >=8.5% and a <=0.5% reduction from Baseline between >=Week 12 and <Week 24; HbA1c >=8.5% between >=Week 24 and <Week 48; HbA1c >=8.0% between >= Week 48 and <Week 156. Participants could have been rescued at any time on or after Week 2. Time to hyperglycemia

	rescue is defined as the time between the date of the first dose of study medication and the date of hyperglycemia rescue plus 1 day, or the time between the date of the first dose of study medication and the date of the last visit during the active treatment period plus 1 day for participants not requiring rescue. This time was divided by 7 to express the result in weeks.
Time Frame	From the start of study medication until the end of the treatment (up to Week 156)
Safety Issue?	No

Analysis Population Description

ITT Population

Reporting Groups

	Description
Placebo + Metformin + Glimepiride	Participants received albiglutide matching placebo as a subcutaneous injection weekly via a fully disposable pen injector system with open-label glimepiride (4 milligrams [mg] daily orally) with metformin (>=1500 mg daily orally). Participants did not receive investigational product during the Follow-up Period.
Pioglitazone + Metformin + Glimepiride	Participants received pioglitazone (30 mg daily orally; with treatment-masked uptitration if needed to 45 mg) and albiglutide-matching placebo weekly as a subcutaneous injection via a fully disposable pen injector system with open-label glimepiride (4 mg daily orally) with metformin (>=1500 mg daily orally). Participants did not receive investigational product during the Follow-up Period.
Albiglutide + Metformin + Glimepiride	Participants received pioglitazone-matching placebo daily orally and albiglutide (30 mg weekly; treatment-masked uptitration if needed to 50 mg weekly) as a subcutaneous injection via a fully disposable pen injector system with open-label glimepiride (4 mg daily orally) with

	Description
	metformin (>=1500 mg daily orally). Participants did not receive investigational product during the Follow-up Period.

Measured Values

	Placebo + Metformin + Glimepiride	Pioglitazone + Metformin + Glimepiride	Albiglutide + Metformin + Glimepiride
Number of Participants Analyzed	115	273	269
Time to Hyperglycemia Rescue [units: Weeks] Median (95% Confidence Interval)	49.57 (38.86 to 55.14)	NA (NA to NA) [1]	137.71 (93.71 to NA) [2]

[1] There were too few events of hyperglycemia rescue (<50% of participants with events) to calculate the median and confidence interval.

[2] The upper bound of the 95% confidence interval is not available because it is beyond the study duration.

6. Secondary Outcome Measure:

Measure Title	Number of Participants Who Achieved Clinically Meaningful HbA1c Response Levels of <6.5%, <7%, and <7.5% at Week 52
Measure Description	The number of participants who acheieved the HbA1c treatment goal (i.e., HbA1c response levels of <6.5%, <7%, and <7.5% at Week 52) was assessed. Values were carried forward for participants who were rescued or discontinued from active treatment before Week 52.
Time Frame	Week 52
Safety Issue?	No

Analysis Population Description

ITT Population with LOCF. Only those participants with a value at Baseline and at the specified visit were analyzed.

Reporting Groups

	Description
Placebo + Metformin + Glimepiride	Participants received albiglutide matching placebo as a subcutaneous injection weekly via a fully disposable pen injector system with open-label glimepiride (4 milligrams [mg] daily orally) with metformin (>=1500 mg daily orally). Participants did not receive investigational product during the Follow-up Period.
Pioglitazone + Metformin + Glimepiride	Participants received pioglitazone (30 mg daily orally; with treatment-masked uptitration if needed to 45 mg) and albiglutide-matching placebo weekly as a subcutaneous injection via a fully disposable pen injector system with open-label glimepiride (4 mg daily orally) with metformin (>=1500 mg daily orally). Participants did not receive investigational product during the Follow-up Period.
Albiglutide + Metformin + Glimepiride	Participants received pioglitazone-matching placebo daily orally and albiglutide (30 mg weekly; treatment-masked uptitration if needed to 50 mg weekly) as a subcutaneous injection via a fully disposable pen injector system with open-label glimepiride (4 mg daily orally) with metformin (>=1500 mg daily orally). Participants did not receive investigational product during the Follow-up Period.

Measured Values

	Placebo + Metformin + Glimepiride	Pioglitazone + Metformin + Glimepiride	Albiglutide + Metformin + Glimepiride
Number of Participants Analyzed	115	268	265
Number of Participants Who Achieved Clinically Meaningful HbA1c Response			

	Placebo + Metformin + Glimepiride	Pioglitazone + Metformin + Glimepiride	Albiglutide + Metformin + Glimepiride
Levels of <6.5%, <7%, and <7.5% at Week 52 [units: Participants]			
HbA1c <6.5%	4	37	27
HbA1c <7.0%	10	94	79
HbA1c <7.5%	19	150	126

7. Secondary Outcome Measure:

Measure Title	Number of Participants Who Achieved Clinically Meaningful HbA1c Response Levels of <6.5%, <7%, and <7.5% at Week 156
Measure Description	The number of participants who acheieved the HbA1c treatment goal (i.e., HbA1c response levels of <6.5%, <7%, and <7.5% at Week 156) was assessed.
Time Frame	Week 156
Safety Issue?	No

Analysis Population Description

ITT Population with observed values. Only those participants with a value at Baseline and at the specified visit were analyzed. This analysis used observed HbA1c values excluding those obtained after hyperglycemia rescue; no missing data imputation was performed.

Reporting Groups

	Description
Placebo + Metformin +	Participants received albiglutide matching placebo as a subcutaneous

	Description
Glimepiride	injection weekly via a fully disposable pen injector system with open-label glimepiride (4 milligrams [mg] daily orally) with metformin (>=1500 mg daily orally). Participants did not receive investigational product during the Follow-up Period.
Pioglitazone + Metformin + Glimepiride	Participants received pioglitazone (30 mg daily orally; with treatment-masked uptitration if needed to 45 mg) and albiglutide-matching placebo weekly as a subcutaneous injection via a fully disposable pen injector system with open-label glimepiride (4 mg daily orally) with metformin (>=1500 mg daily orally). Participants did not receive investigational product during the Follow-up Period.
Albiglutide + Metformin + Glimepiride	Participants received pioglitazone-matching placebo daily orally and albiglutide (30 mg weekly; treatment-masked uptitration if needed to 50 mg weekly) as a subcutaneous injection via a fully disposable pen injector system with open-label glimepiride (4 mg daily orally) with metformin (>=1500 mg daily orally). Participants did not receive investigational product during the Follow-up Period.

Measured Values

	Placebo + Metformin + Glimepiride	Pioglitazone + Metformin + Glimepiride	Albiglutide + Metformin + Glimepiride
Number of Participants Analyzed	9	89	71
Number of Participants Who Achieved Clinically Meaningful HbA1c Response Levels of <6.5%, <7%, and <7.5% at Week 156 [units: Participants]			
HbA1c <6.5%	1	23	16

	Placebo + Metformin + Glimepiride	Pioglitazone + Metformin + Glimepiride	Albiglutide + Metformin + Glimepiride
HbA1c <7.0%	3	44	26
HbA1c <7.5%	5	68	45

8. Secondary Outcome Measure:

Measure Title	Change From Baseline in Body Weight at Week 52
Measure Description	The Baseline value is the last non-missing value before the start of treatment. Change from Baseline was calculated as the post-Baseline weight minus the Baseline weight. The LOCF method was used to impute missing post-Baseline weight values. Weight values obtained after hyperglycemia rescue were treated as missing and replaced with pre-rescue values. Based on ANCOVA: change = treatment + Baseline weight + Baseline HbA1c category + prior myocardial infarction history + age category + region.
Time Frame	Baseline and Week 52
Safety Issue?	No

Analysis Population Description

ITT Population with LOCF. Only those participants with a value at Baseline and at the specified visit were analyzed. Values were carried forward for participants who were rescued or discontinued from active treatment before Week 52.

Reporting Groups

	Description
Placebo + Metformin + Glimepiride	Participants received albiglutide matching placebo as a subcutaneous injection weekly via a fully disposable pen injector system with open-label glimepiride (4 milligrams [mg] daily orally) with metformin (>=1500 mg daily orally). Participants did not receive investigational

	Description
	product during the Follow-up Period.
Pioglitazone + Metformin + Glimepiride	Participants received pioglitazone (30 mg daily orally; with treatment-masked uptitration if needed to 45 mg) and albiglutide-matching placebo weekly as a subcutaneous injection via a fully disposable pen injector system with open-label glimepiride (4 mg daily orally) with metformin (>=1500 mg daily orally). Participants did not receive investigational product during the Follow-up Period.
Albiglutide + Metformin + Glimepiride	Participants received pioglitazone-matching placebo daily orally and albiglutide (30 mg weekly; treatment-masked uptitration if needed to 50 mg weekly) as a subcutaneous injection via a fully disposable pen injector system with open-label glimepiride (4 mg daily orally) with metformin (>=1500 mg daily orally). Participants did not receive investigational product during the Follow-up Period.

Measured Values

	Placebo + Metformin + Glimepiride	Pioglitazone + Metformin + Glimepiride	Albiglutide + Metformin + Glimepiride
Number of Participants Analyzed	115	272	268
Change From Baseline in Body Weight at Week 52 [units: Kilograms] Least Squares Mean (Standard Error)	-0.40 (0.362)	4.43 (0.235)	-0.42 (0.237)

9. Secondary Outcome Measure:

Measure Title	Change From Baseline in Body Weight at Week 104 and Week 156

Measure Description	The Baseline value is the last non-missing value before the start of treatment. Change from Baseline was calculated as the post-Baseline weight minus the Baseline weight. This analysis used observed body weight values excluding those obtained after hyperglycemia rescue; no missing data imputation was performed.
Time Frame	Baseline, Week 104, and Week 156
Safety Issue?	No

Analysis Population Description

ITT Population with observed values. Only those participants with a value at Baseline and at the specified visit were analyzed (represented by n=X, X, X in the category titles).

Reporting Groups

	Description
Placebo + Metformin + Glimepiride	Participants received albiglutide matching placebo as a subcutaneous injection weekly via a fully disposable pen injector system with open-label glimepiride (4 milligrams [mg] daily orally) with metformin (>=1500 mg daily orally). Participants did not receive investigational product during the Follow-up Period.
Pioglitazone + Metformin + Glimepiride	Participants received pioglitazone (30 mg daily orally; with treatment-masked uptitration if needed to 45 mg) and albiglutide-matching placebo weekly as a subcutaneous injection via a fully disposable pen injector system with open-label glimepiride (4 mg daily orally) with metformin (>=1500 mg daily orally). Participants did not receive investigational product during the Follow-up Period.
Albiglutide + Metformin + Glimepiride	Participants received pioglitazone-matching placebo daily orally and albiglutide (30 mg weekly; treatment-masked uptitration if needed to 50 mg weekly) as a subcutaneous injection via a fully disposable pen injector system with open-label glimepiride (4 mg daily orally) with metformin (>=1500 mg daily orally). Participants did not receive

	Description
	investigational product during the Follow-up Period.

Measured Values

	Placebo + Metformin + Glimepiride	Pioglitazone + Metformin + Glimepiride	Albiglutide + Metformin + Glimepiride
Number of Participants Analyzed	12	130	104
Change From Baseline in Body Weight at Week 104 and Week 156 [units: Kilograms] Mean (Standard Deviation)			
Week 104, n=12, 130, 104	-2.16 (3.603)	6.28 (6.189)	-0.90 (3.721)
Week 156, n=9, 90, 71	-4.47 (5.380)	6.52 (6.332)	-1.53 (3.880)

Reported Adverse Events

Reporting Groups

	Description
Placebo + Metformin + Glimepiride	Participants received albiglutide matching placebo as a subcutaneous injection weekly via a fully disposable pen injector system with open-label glimepiride (4 milligrams [mg] daily orally) with metformin (>=1500 mg daily orally). Participants did not receive investigational product during the Follow-up Period.
Pioglitazone + Metformin + Glimepiride	Participants received pioglitazone (30 mg daily orally; with treatment-masked uptitration if needed to 45 mg) and albiglutide-matching placebo weekly as a subcutaneous injection via a fully disposable pen injector system with open-label glimepiride (4 mg

	Description
	daily orally) with metformin (>=1500 mg daily orally). Participants did not receive investigational product during the Follow-up Period.
Albiglutide + Metformin + Glimepiride	Participants received pioglitazone-matching placebo daily orally and albiglutide (30 mg weekly; treatment-masked uptitration if needed to 50 mg weekly) as a subcutaneous injection via a fully disposable pen injector system with open-label glimepiride (4 mg daily orally) with metformin (>=1500 mg daily orally). Participants did not receive investigational product during the Follow-up Period.

Time Frame

On-treatment serious adverse events (SAEs) and non-serious AEs, defined as those events that had a start date on or after the first day of study medication and within 56 days after the end of study medication (up to Week 156), are reported.

Additional Description

SAEs and non-serious AEs are reported for members of the Safety Population, comprised of all participants who received at least one dose of study treatment.

Serious Adverse Events

	Placebo + Metformin + Glimepiride	Pioglitazone + Metformin + Glimepiride	Albiglutide + Metformin + Glimepiride
Total # participants affected/at risk	21/115 (18.26%)	48/277 (17.33%)	39/271 (14.39%)
Blood and lymphatic system disorders			
Anaemia †[A]			
# participants affected/at risk	0/115 (0%)	1/277 (0.36%)	0/271 (0%)

	Placebo + Metformin + Glimepiride	Pioglitazone + Metformin + Glimepiride	Albiglutide + Metformin + Glimepiride
# events			
Lymphadenopathy † [A]			
# participants affected/at risk	0/115 (0%)	0/277 (0%)	1/271 (0.37%)
# events			
Cardiac disorders			
Acute coronary syndrome † [A]			
# participants affected/at risk	0/115 (0%)	1/277 (0.36%)	0/271 (0%)
# events			
Acute myocardial infarction † [A]			
# participants affected/at risk	1/115 (0.87%)	2/277 (0.72%)	0/271 (0%)
# events			
Angina unstable † [A]			
# participants affected/at risk	1/115 (0.87%)	0/277 (0%)	3/271 (1.11%)
# events			
Arteriosclerosis coronary † [A]			
# participants affected/at risk	0/115 (0%)	0/277 (0%)	1/271 (0.37%)

	Placebo + Metformin + Glimepiride	Pioglitazone + Metformin + Glimepiride	Albiglutide + Metformin + Glimepiride
# events			
Atrial fibrillation † [A]			
# participants affected/at risk	0/115 (0%)	1/277 (0.36%)	1/271 (0.37%)
# events			
Cardiac failure † [A]			
# participants affected/at risk	1/115 (0.87%)	0/277 (0%)	0/271 (0%)
# events			
Cardiac failure congestive † [A]			
# participants affected/at risk	1/115 (0.87%)	4/277 (1.44%)	0/271 (0%)
# events			
Coronary artery disease † [A]			
# participants affected/at risk	0/115 (0%)	4/277 (1.44%)	3/271 (1.11%)
# events			
Myocardial infarction † [A]			
# participants affected/at risk	0/115 (0%)	0/277 (0%)	1/271 (0.37%)
# events			

	Placebo + Metformin + Glimepiride	Pioglitazone + Metformin + Glimepiride	Albiglutide + Metformin + Glimepiride
Sick sinus syndrome † [A]			
# participants affected/at risk	0/115 (0%)	1/277 (0.36%)	2/271 (0.74%)
# events			
Eye disorders			
Cataract † [A]			
# participants affected/at risk	0/115 (0%)	1/277 (0.36%)	1/271 (0.37%)
# events			
Gastrointestinal disorders			
Abdominal hernia † [A]			
# participants affected/at risk	0/115 (0%)	0/277 (0%)	2/271 (0.74%)
# events			
Abdominal pain † [A]			
# participants affected/at risk	1/115 (0.87%)	0/277 (0%)	0/271 (0%)
# events			
Constipation † [A]			
# participants affected/at risk	0/115 (0%)	0/277 (0%)	1/271 (0.37%)

	Placebo + Metformin + Glimepiride	Pioglitazone + Metformin + Glimepiride	Albiglutide + Metformin + Glimepiride
# events			
Duodenal ulcer haemorrhage † [A]			
# participants affected/at risk	0/115 (0%)	1/277 (0.36%)	0/271 (0%)
# events			
Pancreatitis † [A]			
# participants affected/at risk	0/115 (0%)	0/277 (0%)	2/271 (0.74%)
# events			
Retroperitoneal haemorrhage † [A]			
# participants affected/at risk	0/115 (0%)	1/277 (0.36%)	0/271 (0%)
# events			
Sigmoiditis † [A]			
# participants affected/at risk	0/115 (0%)	0/277 (0%)	1/271 (0.37%)
# events			
Small intestinal obstruction † [A]			
# participants affected/at risk	0/115 (0%)	1/277 (0.36%)	1/271 (0.37%)

	Placebo + Metformin + Glimepiride	Pioglitazone + Metformin + Glimepiride	Albiglutide + Metformin + Glimepiride
# events			
Vomiting † [A]			
# participants affected/at risk	0/115 (0%)	0/277 (0%)	1/271 (0.37%)
# events			
General disorders			
Chest pain † [A]			
# participants affected/at risk	1/115 (0.87%)	4/277 (1.44%)	2/271 (0.74%)
# events			
Sudden death † [A]			
# participants affected/at risk	0/115 (0%)	0/277 (0%)	1/271 (0.37%)
# events			
Infections and infestations			
Abscess † [A]			
# participants affected/at risk	0/115 (0%)	1/277 (0.36%)	0/271 (0%)
# events			
Cellulitis † [A]			
# participants affected/at	2/115 (1.74%)	1/277 (0.36%)	0/271 (0%)

	Placebo + Metformin + Glimepiride	Pioglitazone + Metformin + Glimepiride	Albiglutide + Metformin + Glimepiride
risk			
# events			
Diabetic foot infection † [A]			
# participants affected/at risk	1/115 (0.87%)	0/277 (0%)	1/271 (0.37%)
# events			
Febrile infection † [A]			
# participants affected/at risk	1/115 (0.87%)	0/277 (0%)	0/271 (0%)
# events			
Gangrene † [A]			
# participants affected/at risk	0/115 (0%)	1/277 (0.36%)	0/271 (0%)
# events			
Gastroenteritis † [A]			
# participants affected/at risk	0/115 (0%)	0/277 (0%)	1/271 (0.37%)
# events			
Gastroenteritis viral † [A]			
# participants affected/at risk	1/115 (0.87%)	0/277 (0%)	0/271 (0%)
# events			

	Placebo + Metformin + Glimepiride	Pioglitazone + Metformin + Glimepiride	Albiglutide + Metformin + Glimepiride
Infected bites † [A]			
# participants affected/at risk	0/115 (0%)	0/277 (0%)	1/271 (0.37%)
# events			
Influenza † [A]			
# participants affected/at risk	1/115 (0.87%)	0/277 (0%)	0/271 (0%)
# events			
Lobar pneumonia † [A]			
# participants affected/at risk	1/115 (0.87%)	0/277 (0%)	0/271 (0%)
# events			
Localised infection † [A]			
# participants affected/at risk	0/115 (0%)	1/277 (0.36%)	0/271 (0%)
# events			
Meningitis pneumococcal † [A]			
# participants affected/at risk	1/115 (0.87%)	0/277 (0%)	0/271 (0%)
# events			
Pancreatitis viral † [A]			

	Placebo + Metformin + Glimepiride	Pioglitazone + Metformin + Glimepiride	Albiglutide + Metformin + Glimepiride
# participants affected/at risk	0/115 (0%)	0/277 (0%)	1/271 (0.37%)
# events			
Peritonitis †[A]			
# participants affected/at risk	0/115 (0%)	1/277 (0.36%)	0/271 (0%)
# events			
Pneumonia †[A]			
# participants affected/at risk	2/115 (1.74%)	1/277 (0.36%)	2/271 (0.74%)
# events			
Postoperative wound infection †[A]			
# participants affected/at risk	0/115 (0%)	1/277 (0.36%)	0/271 (0%)
# events			
Septic shock †[A]			
# participants affected/at risk	0/115 (0%)	1/277 (0.36%)	0/271 (0%)
# events			
Tracheobronchitis †[A]			
# participants affected/at risk	0/115 (0%)	0/277 (0%)	1/271 (0.37%)

	Placebo + Metformin + Glimepiride	Pioglitazone + Metformin + Glimepiride	Albiglutide + Metformin + Glimepiride
# events			
Injury, poisoning and procedural complications			
Ankle fracture † [A]			
# participants affected/at risk	0/115 (0%)	1/277 (0.36%)	0/271 (0%)
# events			
Overdose † [A]			
# participants affected/at risk	0/115 (0%)	0/277 (0%)	1/271 (0.37%)
# events			
Road traffic accident † [A]			
# participants affected/at risk	1/115 (0.87%)	0/277 (0%)	0/271 (0%)
# events			
Thoracic vertebral fracture † [A]			
# participants affected/at risk	0/115 (0%)	0/277 (0%)	1/271 (0.37%)
# events			
Metabolism and nutrition disorders			

	Placebo + Metformin + Glimepiride	Pioglitazone + Metformin + Glimepiride	Albiglutide + Metformin + Glimepiride
Fluid overload †[A]			
# participants affected/at risk	0/115 (0%)	1/277 (0.36%)	0/271 (0%)
# events			
Gout †[A]			
# participants affected/at risk	1/115 (0.87%)	0/277 (0%)	0/271 (0%)
# events			
Hypoglycaemia †[A]			
# participants affected/at risk	1/115 (0.87%)	2/277 (0.72%)	0/271 (0%)
# events			
Musculoskeletal and connective tissue disorders			
Back pain †[A]			
# participants affected/at risk	1/115 (0.87%)	1/277 (0.36%)	0/271 (0%)
# events			
Muscle spasms †[A]			
# participants affected/at risk	0/115 (0%)	0/277 (0%)	1/271 (0.37%)

	Placebo + Metformin + Glimepiride	Pioglitazone + Metformin + Glimepiride	Albiglutide + Metformin + Glimepiride
# events			
Musculoskeletal chest pain † [A]			
# participants affected/at risk	0/115 (0%)	1/277 (0.36%)	0/271 (0%)
# events			
Musculoskeletal pain † [A]			
# participants affected/at risk	0/115 (0%)	1/277 (0.36%)	0/271 (0%)
# events			
Osteoarthritis † [A]			
# participants affected/at risk	0/115 (0%)	1/277 (0.36%)	2/271 (0.74%)
# events			
Spinal column stenosis † [A]			
# participants affected/at risk	0/115 (0%)	0/277 (0%)	1/271 (0.37%)
# events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			

	Placebo + Metformin + Glimepiride	Pioglitazone + Metformin + Glimepiride	Albiglutide + Metformin + Glimepiride
Adenocarcinoma pancreas † [A]			
# participants affected/at risk	0/115 (0%)	1/277 (0.36%)	0/271 (0%)
# events			
Bile duct cancer † [A]			
# participants affected/at risk	0/115 (0%)	0/277 (0%)	1/271 (0.37%)
# events			
Bladder cancer † [A]			
# participants affected/at risk	0/115 (0%)	1/277 (0.36%)	0/271 (0%)
# events			
Bladder neoplasm † [A]			
# participants affected/at risk	0/115 (0%)	1/277 (0.36%)	0/271 (0%)
# events			
Breast cancer † [A]			
# participants affected/at risk	0/115 (0%)	1/277 (0.36%)	0/271 (0%)
# events			
Endometrial cancer † [A]			

	Placebo + Metformin + Glimepiride	Pioglitazone + Metformin + Glimepiride	Albiglutide + Metformin + Glimepiride
# participants affected/at risk	0/115 (0%)	1/277 (0.36%)	0/271 (0%)
# events			
Lung neoplasm malignant † [A]			
# participants affected/at risk	0/115 (0%)	1/277 (0.36%)	0/271 (0%)
# events			
Prostate cancer † [A]			
# participants affected/at risk	1/115 (0.87%)	0/277 (0%)	0/271 (0%)
# events			
Rectal cancer † [A]			
# participants affected/at risk	0/115 (0%)	0/277 (0%)	1/271 (0.37%)
# events			
Renal cancer † [A]			
# participants affected/at risk	0/115 (0%)	1/277 (0.36%)	0/271 (0%)
# events			
Thyroid adenoma † [A]			
# participants affected/at risk	0/115 (0%)	1/277 (0.36%)	0/271 (0%)

	Placebo + Metformin + Glimepiride	Pioglitazone + Metformin + Glimepiride	Albiglutide + Metformin + Glimepiride
# events			
Thyroid cancer † [A]			
# participants affected/at risk	1/115 (0.87%)	0/277 (0%)	0/271 (0%)
# events			
Uterine cancer † [A]			
# participants affected/at risk	0/115 (0%)	1/277 (0.36%)	0/271 (0%)
# events			
Uterine leiomyoma † [A]			
# participants affected/at risk	0/115 (0%)	0/277 (0%)	1/271 (0.37%)
# events			
Nervous system disorders			
Carotid artery stenosis † [A]			
# participants affected/at risk	0/115 (0%)	2/277 (0.72%)	0/271 (0%)
# events			
Cerebrovascular accident † [A]			
# participants affected/at	1/115 (0.87%)	3/277 (1.08%)	0/271 (0%)

	Placebo + Metformin + Glimepiride	Pioglitazone + Metformin + Glimepiride	Albiglutide + Metformin + Glimepiride
risk			
# events			
Haemorrhagic stroke †[A]			
# participants affected/at risk	0/115 (0%)	1/277 (0.36%)	0/271 (0%)
# events			
Headache †[A]			
# participants affected/at risk	0/115 (0%)	1/277 (0.36%)	0/271 (0%)
# events			
Hypertensive encephalopathy †[A]			
# participants affected/at risk	0/115 (0%)	1/277 (0.36%)	0/271 (0%)
# events			
Hypoaesthesia †[A]			
# participants affected/at risk	0/115 (0%)	0/277 (0%)	1/271 (0.37%)
# events			
Ischaemic stroke †[A]			
# participants affected/at risk	1/115 (0.87%)	0/277 (0%)	0/271 (0%)

	Placebo + Metformin + Glimepiride	Pioglitazone + Metformin + Glimepiride	Albiglutide + Metformin + Glimepiride
# events			
Metabolic encephalopathy † [A]			
# participants affected/at risk	1/115 (0.87%)	0/277 (0%)	0/271 (0%)
# events			
Migraine † [A]			
# participants affected/at risk	0/115 (0%)	1/277 (0.36%)	0/271 (0%)
# events			
Myelitis transverse † [A]			
# participants affected/at risk	0/115 (0%)	0/277 (0%)	1/271 (0.37%)
# events			
Nerve compression † [A]			
# participants affected/at risk	0/115 (0%)	1/277 (0.36%)	0/271 (0%)
# events			
Transient ischaemic attack † [A]			
# participants affected/at risk	0/115 (0%)	2/277 (0.72%)	0/271 (0%)
# events			

	Placebo + Metformin + Glimepiride	Pioglitazone + Metformin + Glimepiride	Albiglutide + Metformin + Glimepiride
Trigeminal neuralgia † [A]			
# participants affected/at risk	0/115 (0%)	1/277 (0.36%)	0/271 (0%)
# events			
Vith nerve paralysis † [A]			
# participants affected/at risk	0/115 (0%)	1/277 (0.36%)	0/271 (0%)
# events			
Psychiatric disorders			
Bipolar disorder † [A]			
# participants affected/at risk	0/115 (0%)	0/277 (0%)	1/271 (0.37%)
# events			
Major depression † [A]			
# participants affected/at risk	0/115 (0%)	1/277 (0.36%)	0/271 (0%)
# events			
Panic disorder † [A]			
# participants affected/at risk	0/115 (0%)	0/277 (0%)	1/271 (0.37%)
# events			
Suicidal ideation † [A]			

	Placebo + Metformin + Glimepiride	Pioglitazone + Metformin + Glimepiride	Albiglutide + Metformin + Glimepiride
# participants affected/at risk	0/115 (0%)	1/277 (0.36%)	0/271 (0%)
# events			
Renal and urinary disorders			
Glomerulonephritis acute † [A]			
# participants affected/at risk	1/115 (0.87%)	0/277 (0%)	0/271 (0%)
# events			
Nephrolithiasis † [A]			
# participants affected/at risk	3/115 (2.61%)	0/277 (0%)	0/271 (0%)
# events			
Respiratory, thoracic and mediastinal disorders			
Pneumothorax † [A]			
# participants affected/at risk	1/115 (0.87%)	0/277 (0%)	0/271 (0%)
# events			
Pulmonary embolism † [A]			
# participants affected/at	1/115 (0.87%)	0/277 (0%)	0/271 (0%)

	Placebo + Metformin + Glimepiride	Pioglitazone + Metformin + Glimepiride	Albiglutide + Metformin + Glimepiride
risk			
# events			
Respiratory failure † [A]			
# participants affected/at risk	1/115 (0.87%)	1/277 (0.36%)	0/271 (0%)
# events			
Vascular disorders			
Hypertensive crisis † [A]			
# participants affected/at risk	0/115 (0%)	0/277 (0%)	2/271 (0.74%)
# events			
Peripheral artery stenosis † [A]			
# participants affected/at risk	0/115 (0%)	0/277 (0%)	1/271 (0.37%)
# events			

† Indicates events were collected by systematic assessment.

A Term from vocabulary, MedDRA

Other Adverse Events

Frequency Threshold Above Which Other Adverse Events are Reported: 2%

	Placebo + Metformin + Glimepiride	Pioglitazone + Metformin + Glimepiride	Albiglutide + Metformin + Glimepiride
Total # participants affected/at risk	81/115 (70.43%)	228/277 (82.31%)	228/271 (84.13%)
Blood and lymphatic system disorders			
Anaemia †[A]			
# participants affected/at risk	4/115 (3.48%)	24/277 (8.66%)	13/271 (4.8%)
# events			
Leukocytosis †[A]			
# participants affected/at risk	3/115 (2.61%)	0/277 (0%)	2/271 (0.74%)
# events			
Ear and labyrinth disorders			
Vertigo †[A]			
# participants affected/at risk	1/115 (0.87%)	7/277 (2.53%)	9/271 (3.32%)
# events			
Eye disorders			
Cataract †[A]			
# participants affected/at risk	3/115 (2.61%)	13/277 (4.69%)	8/271 (2.95%)

	Placebo + Metformin + Glimepiride	Pioglitazone + Metformin + Glimepiride	Albiglutide + Metformin + Glimepiride
# events			
Diabetic retinopathy † [A]			
# participants affected/at risk	3/115 (2.61%)	17/277 (6.14%)	10/271 (3.69%)
# events			
Gastrointestinal disorders			
Abdominal distension † [A]			
# participants affected/at risk	3/115 (2.61%)	4/277 (1.44%)	3/271 (1.11%)
# events			
Abdominal pain † [A]			
# participants affected/at risk	2/115 (1.74%)	7/277 (2.53%)	17/271 (6.27%)
# events			
Abdominal pain upper † [A]			
# participants affected/at risk	1/115 (0.87%)	7/277 (2.53%)	6/271 (2.21%)
# events			
Constipation † [A]			
# participants affected/at risk	7/115 (6.09%)	11/277 (3.97%)	14/271 (5.17%)

	Placebo + Metformin + Glimepiride	Pioglitazone + Metformin + Glimepiride	Albiglutide + Metformin + Glimepiride
# events			
Diarrhoea † [A]			
# participants affected/at risk	12/115 (10.43%)	23/277 (8.3%)	37/271 (13.65%)
# events			
Dyspepsia † [A]			
# participants affected/at risk	1/115 (0.87%)	2/277 (0.72%)	10/271 (3.69%)
# events			
Gastritis † [A]			
# participants affected/at risk	3/115 (2.61%)	5/277 (1.81%)	5/271 (1.85%)
# events			
Gastrooesophageal reflux disease † [A]			
# participants affected/at risk	3/115 (2.61%)	9/277 (3.25%)	12/271 (4.43%)
# events			
Nausea † [A]			
# participants affected/at risk	7/115 (6.09%)	20/277 (7.22%)	30/271 (11.07%)
# events			

	Placebo + Metformin + Glimepiride	Pioglitazone + Metformin + Glimepiride	Albiglutide + Metformin + Glimepiride
Toothache †[A]			
# participants affected/at risk	1/115 (0.87%)	9/277 (3.25%)	4/271 (1.48%)
# events			
Vomiting †[A]			
# participants affected/at risk	4/115 (3.48%)	14/277 (5.05%)	6/271 (2.21%)
# events			
General disorders			
Chest pain †[A]			
# participants affected/at risk	3/115 (2.61%)	4/277 (1.44%)	2/271 (0.74%)
# events			
Fatigue †[A]			
# participants affected/at risk	6/115 (5.22%)	15/277 (5.42%)	8/271 (2.95%)
# events			
Injection site reaction †[A]			
# participants affected/at risk	1/115 (0.87%)	8/277 (2.89%)	32/271 (11.81%)
# events			
Oedema †[A]			

	Placebo + Metformin + Glimepiride	Pioglitazone + Metformin + Glimepiride	Albiglutide + Metformin + Glimepiride
# participants affected/at risk	0/115 (0%)	8/277 (2.89%)	1/271 (0.37%)
# events			
Oedema peripheral † [A]			
# participants affected/at risk	9/115 (7.83%)	41/277 (14.8%)	12/271 (4.43%)
# events			
Immune system disorders			
Seasonal allergy † [A]			
# participants affected/at risk	3/115 (2.61%)	4/277 (1.44%)	5/271 (1.85%)
# events			
Infections and infestations			
Bronchitis † [A]			
# participants affected/at risk	7/115 (6.09%)	25/277 (9.03%)	16/271 (5.9%)
# events			
Cellulitis † [A]			
# participants affected/at risk	2/115 (1.74%)	13/277 (4.69%)	2/271 (0.74%)

	Placebo + Metformin + Glimepiride	Pioglitazone + Metformin + Glimepiride	Albiglutide + Metformin + Glimepiride
# events			
Furuncle † [A]			
# participants affected/at risk	0/115 (0%)	2/277 (0.72%)	6/271 (2.21%)
# events			
Gastroenteritis † [A]			
# participants affected/at risk	5/115 (4.35%)	10/277 (3.61%)	9/271 (3.32%)
# events			
Gastroenteritis viral † [A]			
# participants affected/at risk	2/115 (1.74%)	3/277 (1.08%)	6/271 (2.21%)
# events			
Herpes zoster † [A]			
# participants affected/at risk	3/115 (2.61%)	1/277 (0.36%)	4/271 (1.48%)
# events			
Influenza † [A]			
# participants affected/at risk	5/115 (4.35%)	10/277 (3.61%)	16/271 (5.9%)
# events			
Nasopharyngitis † [A]			

	Placebo + Metformin + Glimepiride	Pioglitazone + Metformin + Glimepiride	Albiglutide + Metformin + Glimepiride
# participants affected/at risk	16/115 (13.91%)	28/277 (10.11%)	43/271 (15.87%)
# events			
Pharyngitis †[A]			
# participants affected/at risk	5/115 (4.35%)	9/277 (3.25%)	8/271 (2.95%)
# events			
Sinusitis †[A]			
# participants affected/at risk	7/115 (6.09%)	16/277 (5.78%)	18/271 (6.64%)
# events			
Tooth abscess †[A]			
# participants affected/at risk	4/115 (3.48%)	3/277 (1.08%)	5/271 (1.85%)
# events			
Upper respiratory tract infection †[A]			
# participants affected/at risk	21/115 (18.26%)	50/277 (18.05%)	34/271 (12.55%)
# events			
Urinary tract infection †[A]			
# participants affected/at risk	9/115 (7.83%)	31/277 (11.19%)	24/271 (8.86%)

	Placebo + Metformin + Glimepiride	Pioglitazone + Metformin + Glimepiride	Albiglutide + Metformin + Glimepiride
# events			
Injury, poisoning and procedural complications			
Contusion † [A]			
# participants affected/at risk	5/115 (4.35%)	8/277 (2.89%)	7/271 (2.58%)
# events			
Excoriation † [A]			
# participants affected/at risk	6/115 (5.22%)	7/277 (2.53%)	4/271 (1.48%)
# events			
Ligament sprain † [A]			
# participants affected/at risk	2/115 (1.74%)	4/277 (1.44%)	8/271 (2.95%)
# events			
Muscle strain † [A]			
# participants affected/at risk	5/115 (4.35%)	6/277 (2.17%)	7/271 (2.58%)
# events			
Procedural pain † [A]			
# participants affected/at risk	1/115 (0.87%)	8/277 (2.89%)	3/271 (1.11%)

	Placebo + Metformin + Glimepiride	Pioglitazone + Metformin + Glimepiride	Albiglutide + Metformin + Glimepiride
# events			
Rib Fracture † [A]			
# participants affected/at risk	3/115 (2.61%)	1/277 (0.36%)	2/271 (0.74%)
# events			
Investigations			
Blood creatinine increased † [A]			
# participants affected/at risk	1/115 (0.87%)	6/277 (2.17%)	1/271 (0.37%)
# events			
Cardiac murmur † [A]			
# participants affected/at risk	0/115 (0%)	3/277 (1.08%)	6/271 (2.21%)
# events			
Gamma-glutamyltransferase increased † [A]			
# participants affected/at risk	1/115 (0.87%)	1/277 (0.36%)	6/271 (2.21%)
# events			
Weight increased † [A]			
# participants affected/at risk	0/115 (0%)	21/277 (7.58%)	0/271 (0%)

	Placebo + Metformin + Glimepiride	Pioglitazone + Metformin + Glimepiride	Albiglutide + Metformin + Glimepiride
# events			
Metabolism and nutrition disorders			
Decreased appetite †[A]			
# participants affected/at risk	3/115 (2.61%)	3/277 (1.08%)	5/271 (1.85%)
# events			
Dyslipidaemia †[A]			
# participants affected/at risk	1/115 (0.87%)	4/277 (1.44%)	7/271 (2.58%)
# events			
Hyperlipidaemia †[A]			
# participants affected/at risk	3/115 (2.61%)	4/277 (1.44%)	4/271 (1.48%)
# events			
Hypoglycaemia †[A]			
# participants affected/at risk	28/115 (24.35%)	115/277 (41.52%)	84/271 (31%)
# events			
Musculoskeletal and connective tissue disorders			

	Placebo + Metformin + Glimepiride	Pioglitazone + Metformin + Glimepiride	Albiglutide + Metformin + Glimepiride
Arthralgia †[A]			
# participants affected/at risk	9/115 (7.83%)	23/277 (8.3%)	26/271 (9.59%)
# events			
Back pain †[A]			
# participants affected/at risk	8/115 (6.96%)	24/277 (8.66%)	24/271 (8.86%)
# events			
Muscle spasms †[A]			
# participants affected/at risk	3/115 (2.61%)	7/277 (2.53%)	12/271 (4.43%)
# events			
Musculoskeletal chest pain †[A]			
# participants affected/at risk	3/115 (2.61%)	4/277 (1.44%)	2/271 (0.74%)
# events			
Musculoskeletal pain †[A]			
# participants affected/at risk	6/115 (5.22%)	12/277 (4.33%)	11/271 (4.06%)
# events			
Myalgia †[A]			

	Placebo + Metformin + Glimepiride	Pioglitazone + Metformin + Glimepiride	Albiglutide + Metformin + Glimepiride
# participants affected/at risk	4/115 (3.48%)	8/277 (2.89%)	4/271 (1.48%)
# events			
Osteoarthritis † [A]			
# participants affected/at risk	2/115 (1.74%)	11/277 (3.97%)	8/271 (2.95%)
# events			
Pain in extremity † [A]			
# participants affected/at risk	5/115 (4.35%)	14/277 (5.05%)	12/271 (4.43%)
# events			
Tendonitis † [A]			
# participants affected/at risk	3/115 (2.61%)	4/277 (1.44%)	5/271 (1.85%)
# events			
Nervous system disorders			
Diabetic neuropathy † [A]			
# participants affected/at risk	4/115 (3.48%)	4/277 (1.44%)	4/271 (1.48%)
# events			
Dizziness † [A]			

	Placebo + Metformin + Glimepiride	Pioglitazone + Metformin + Glimepiride	Albiglutide + Metformin + Glimepiride
# participants affected/at risk	6/115 (5.22%)	9/277 (3.25%)	16/271 (5.9%)
# events			
Headache †[A]			
# participants affected/at risk	6/115 (5.22%)	25/277 (9.03%)	21/271 (7.75%)
# events			
Hypoaesthesia †[A]			
# participants affected/at risk	1/115 (0.87%)	7/277 (2.53%)	7/271 (2.58%)
# events			
Neuropathy peripheral †[A]			
# participants affected/at risk	1/115 (0.87%)	12/277 (4.33%)	13/271 (4.8%)
# events			
Psychiatric disorders			
Anxiety †[A]			
# participants affected/at risk	1/115 (0.87%)	7/277 (2.53%)	9/271 (3.32%)
# events			
Depression †[A]			
# participants affected/at	3/115 (2.61%)	12/277	5/271 (1.85%)

	Placebo + Metformin + Glimepiride	Pioglitazone + Metformin + Glimepiride	Albiglutide + Metformin + Glimepiride
risk		(4.33%)	
# events			
Insomnia † [A]			
# participants affected/at risk	2/115 (1.74%)	9/277 (3.25%)	11/271 (4.06%)
# events			
Reproductive system and breast disorders			
Benign prostatic hyperplasia † [A]			
# participants affected/at risk	4/115 (3.48%)	3/277 (1.08%)	2/271 (0.74%)
# events			
Respiratory, thoracic and mediastinal disorders			
Asthma † [A]			
# participants affected/at risk	0/115 (0%)	2/277 (0.72%)	7/271 (2.58%)
# events			
Cough † [A]			
# participants affected/at risk	10/115 (8.7%)	19/277 (6.86%)	28/271 (10.33%)

	Placebo + Metformin + Glimepiride	Pioglitazone + Metformin + Glimepiride	Albiglutide + Metformin + Glimepiride
# events			
Dyspnoea † [A]			
# participants affected/at risk	2/115 (1.74%)	9/277 (3.25%)	5/271 (1.85%)
# events			
Rhinitis allergic † [A]			
# participants affected/at risk	1/115 (0.87%)	6/277 (2.17%)	2/271 (0.74%)
# events			
Skin and subcutaneous tissue disorders			
Dermatitis Contact † [A]			
# participants affected/at risk	1/115 (0.87%)	6/277 (2.17%)	2/271 (0.74%)
# events			
Dry Skin † [A]			
# participants affected/at risk	3/115 (2.61%)	2/277 (0.72%)	2/271 (0.74%)
# events			
Rash † [A]			
# participants affected/at risk	4/115 (3.48%)	9/277 (3.25%)	5/271 (1.85%)

	Placebo + Metformin + Glimepiride	Pioglitazone + Metformin + Glimepiride	Albiglutide + Metformin + Glimepiride
# events			
Vascular disorders			
Hypertension † [A]			
# participants affected/at risk	11/115 (9.57%)	27/277 (9.75%)	22/271 (8.12%)
# events			

† Indicates events were collected by systematic assessment.

A Term from vocabulary, MedDRA

More Information

Certain Agreements:

Principal Investigators are NOT employed by the organization sponsoring the study.

There IS an agreement between the Principal Investigator and the Sponsor (or its agents) that restricts the PI's rights to discuss or publish trial results after the trial is completed.

GSK agreements may vary with individual investigators, but will not prohibit any investigator from publishing. GSK supports the publication of results from all centers of a multi-center trial but requests that reports based on single-site data not precede the primary publication of the entire clinical trial.

Limitations and Caveats:

Results Point of Contact:

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