ClinicalTrials.gov Protocol and Results Registration System (PRS) Receipt
Release Date: 08/09/2013

ClinicalTrials.gov ID: NCT00680745

Study Identification

Unique Protocol ID:	D1690C00005
Brief Title:	Efficacy and Safety of Dapagliflozin in Combination With Glimepiride (a Sulphonylurea) in Type 2 Diabetes Patients
Official Title:	A 24-Week,Int.,Rand.,Double-blind,Parallel-group,Multi-centre, Plac.-Controlled Phase III Study With a 24-Wk Ext.Per.to Eval.the Efficacy and Safety of Dapagliflozin in Comb.With Glimepiride (a Sulphonylurea) in Subjects With Type2 Diab.Who Have Inadeq. Glycaemic Control on Glimepiride Therapy Alone
Secondary IDs:	

Study Status

Record Verification:	August 2013
Overall Status:	Completed
Study Start:	April 2008
Primary Completion:	November 2009 [Actual]
Study Completion:	May 2010 [Actual]

Sponsor/Collaborators

Sponsor:	AstraZeneca
Responsible Party:	Sponsor
Collaborators:	Bristol-Myers Squibb

Oversight

FDA Regulated?:	Yes

Applicable Trial?:	Section 801 Clinical Trial? Yes Delayed Posting? No
IND/IDE Protocol?:	No
Review Board:	Approval Status: Approved Approval Number: 3306-0/2008-1017EKL Board Name: Medical Research CouncilEthics Committee for Clinical Pharmacology Board Affiliation: Hungarian Ministry of Health Phone: +36-1-301-7871 Email: magyari.ilona@euem.hu
Data Monitoring?:	No
Plan to Share Data?:	
Oversight Authorities:	Czech Republic: State Institute for Drug Control Hungary: National Institute of Pharmacy India: Central Drugs Standard Control Organization India: Ministry of Health Korea: Food and Drug Administration Philippines: Bureau of Food and Drugs Poland: Ministry of Health Thailand: Food and Drug Administration Ukraine: State Pharmacological Center - Ministry of Health

Study Description

Brief Summary:	This study is being carried out to see if dapagliflozin in addition to glimepiride (sulphonylurea) is effective and safe in treating patients with type 2 diabetes when compared to glimepiride alone.
Detailed Description:	

Conditions

Conditions:	Type 2 Diabetes
Keywords:	Dapagliflozin efficacy safety sulphonylurea Type 2 diabetes

Study Design

Study Type:	Interventional
Primary Purpose:	Treatment
Study Phase:	Phase 3
Intervention Model:	Parallel Assignment
Number of Arms:	4
Masking:	Double Blind (Subject, Caregiver, Investigator, Outcomes Assessor)
Allocation:	Randomized
Endpoint Classification:	Safety/Efficacy Study
Enrollment:	597 [Actual]

Arms and Interventions

Arms	Assigned Interventions
Experimental: 1 dapagliflozin 2.5mg + Glimepiride	Drug: dapagliflozin tablet oral 2.5, 5, or 10 mg total daily dose once daily 48 weeks Drug: Glimepiride tablet oral 2.5, 5, or 10 mg total daily dose once daily 48 weeks Other Names: • Amaryl Drug: metformin hydrochloride rescue medication oral dosing in accordance with the manufacturer's recommendations and clinical practice Other Names: • Glucophage Drug: pioglitazone hydrochloride rescue medication oral dosing in accordance with the manufacturer's recommendations and clinical practice Other Names: • Actos Drug: Rosiglitazone rescue medication oral dosing in accordance with the manufacturer's recommendations and clinical practice Other Names: • Avandia

Arms	Assigned Interventions
Experimental: 2 dapagliflozin 5mg + Glimepiride	Drug: dapagliflozin tablet oral 2.5, 5, or 10 mg total daily dose once daily 48 weeks Drug: Glimepiride tablet oral 2.5, 5, or 10 mg total daily dose once daily 48 weeks Other Names: • Amaryl Drug: metformin hydrochloride rescue medication oral dosing in accordance with the manufacturer's recommendations and clinical practice Other Names: • Glucophage Drug: pioglitazone hydrochloride rescue medication oral dosing in accordance with the manufacturer's recommendations and clinical practice Other Names: • Actos Drug: Rosiglitazone rescue medication oral dosing in accordance with the manufacturer's recommendations and clinical practice Other Names: • Avandia
Experimental: 3 dapagliflozin 10mg + Glimepiride	Drug: dapagliflozin tablet oral 2.5, 5, or 10 mg total daily dose once daily 48 weeks Drug: Glimepiride tablet oral 2.5, 5, or 10 mg total daily dose once daily 48 weeks Other Names: • Amaryl Drug: metformin hydrochloride rescue medication oral dosing in accordance with the manufacturer's recommendations and clinical practice Other Names: • Glucophage Drug: pioglitazone hydrochloride rescue medication oral dosing in accordance with the manufacturer's recommendations and clinical practice Other Names: • Actos

Arms	Assigned Interventions
	Drug: Rosiglitazone rescue medication oral dosing in accordance with the manufacturer's recommendations and clinical practice Other Names: • Avandia
Placebo Comparator: 4 Placebo + Glimepiride	Drug: Glimepiride tablet oral 2.5, 5, or 10 mg total daily dose once daily 48 weeks Other Names: • Amaryl Drug: metformin hydrochloride rescue medication oral dosing in accordance with the manufacturer's recommendations and clinical practice Other Names: • Glucophage Drug: pioglitazone hydrochloride rescue medication oral dosing in accordance with the manufacturer's recommendations and clinical practice Other Names: • Actos Drug: Rosiglitazone rescue medication oral dosing in accordance with the manufacturer's recommendations and clinical practice Other Names: • Avandia

Outcome Measures

[See Results Section.]

Eligibility

Minimum Age: 18 Years

Maximum Age:

Gender: Both

Accepts Healthy Volunteers?: No

Criteria: Inclusion Criteria:

- Type 2 Diabetes
- Treatment with a stable sulphonylurea monotherapy dose that is at least half the maximal recommended dose for a minimum of 8 weeks prior to study
- Inadequate glycaemic control, defined as A1C ≥ 7.0 % and ≤ 10%

Exclusion Criteria:

- Type 1 Diabetes
- Hepatic (liver) impairment
- Renal (kidney) failure or dysfunction

Contacts/Locations

Study Officials: Krzysztof Strojek, Prof. Dr.
Study Principal Investigator
Silesian Medical University3-Maja 13/15, 41-800 Zabrze; Poland

Locations: Czech Republic
Research Site
Blansko, Czech Republic

Research Site
Breclav, Czech Republic

Research Site
Bruntal, Czech Republic

Research Site
Hodonin, Czech Republic

Research Site
Ostrava - Belsky Les, Czech Republic

Research Site
Plzen, Czech Republic

Research Site
Praha 1, Czech Republic

Research Site
Pribram Viii, Czech Republic

Research Site
Rakovnik, Czech Republic

Research Site
Semily, Czech Republic

Hungary
Research Site
Balatonfured, Hungary

Research Site
Bekescsaba, Hungary

Research Site
Budapest, Hungary

Research Site
Csongrad, Hungary

Research Site
Eger, Hungary

Research Site
Gyongyos, Hungary

Research Site
Kecskemet, Hungary

Research Site
Mako, Hungary

Research Site
Miskolc, Hungary

Research Site
Mosonmagyarovar, Hungary

Research Site
Siofok, Hungary

Research Site
Szentes, Hungary

Research Site
TAT, Hungary

Research Site
Zalaegerszeg, Hungary

Philippines
Research Site
Pasig City, Philippines

Research Site
Cebu City, Philippines

Research Site
Manila, Philippines

Research Site
Marikina City, Philippines

Poland
Research Site
Bielsko - Biala, Poland

Research Site
Bydgoszcz, Poland

Research Site
Chojnice, Poland

Research Site
Chrzanow, Poland

Research Site
Ciechocinek, Poland

Research Site
Czechowice-Dziedzice, Poland

Research Site
Elblag, Poland

Research Site
Gdansk, Poland

Research Site
Gniewkowo, Poland

Research Site
Grudziadz, Poland

Research Site
Ilawa, Poland

Research Site
Krakow, Poland

Research Site
Mragowo, Poland

Research Site
Plock, Poland

Research Site
Poznan, Poland

Research Site
Ruda Slaska, Poland

Research Site
Sopot, Poland

Research Site
Torun, Poland

Research Site
Wroclaw, Poland

Research Site
Zabrze, Poland

Research Site
Zielona Gora, Poland

Research Site
Zory, Poland

Korea, Republic of
Research Site
Jeonju, Chonbuk, Korea, Republic of

Research Site
Wonju, Kangwon-do, Korea, Republic of

Research Site
Suwon, Kyunggi-do, Korea, Republic of

Research Site
Bucheon, Korea, Republic of

Research Site
Incheon, Korea, Republic of

Research Site
Seongnam, Korea, Republic of

Research Site
Seoul, Korea, Republic of

Research Site
Uljeongbu, Korea, Republic of

Thailand
Research Site
Bangkok, Thailand

Research Site
Chiang Mai, Thailand

Ukraine
Research Site
Dnipropetrov'sk, Ukraine

Research Site
Donetsk, Ukraine

Research Site
Kharkiv, Ukraine

Research Site
Kiev, Ukraine

Research Site
Vinnytsia, Ukraine

Research Site
Zaporozhye, Ukraine

References

Citations:

Links:

Study Data/Documents:

Study Results

Participant Flow

Recruitment Details	Enrollment: 859 (597 randomized and 592 in the Full Analysis Set) Study Start Date:April 2008 Study Completion Date:May 2010 Primary Completion Date: November 2009 (Final data collection date for primary outcome measure)
Pre-Assignment Details	Reasons for enrolled participants not being randomised: 229 incorrect enrollment, 4 adverse event, 23 withdrew consent, 2 lost to follow up and 4 other.

Reporting Groups

	Description
Dapagliflozin 2.5mg + Glimepiride	Dapagliflozin tablet 2.5 mg once daily plus glimepiride
Dapagliflozin 5mg + Glimepiride	Dapagliflozin tablet 5 mg once daily plus glimepiride
Dapagliflozin 10mg + Glimepiride	Dapagliflozin tablet 10 mg once daily plus glimepiride
Placebo + Glimepiride	Placebo comparator plus glimepiride

Overall Study

	Dapagliflozin 2.5mg + Glimepiride	Dapagliflozin 5mg + Glimepiride	Dapagliflozin 10mg + Glimepiride	Placebo + Glimepiride
Started	154 [1]	145 [1]	151 [1]	146 [1]
Completed	140	132	141	133
Not Completed	14	13	10	13
Withdrawal by Subject	8	3	2	8
Lost to Follow-up	0	1	1	0
Death	1	0	1	0
Adverse Event	5	3	3	3
Poor/Non-compliance	0	3	0	0
Subject No Longer Meets Study Criteria	0	2	0	2
False Treatment	0	1	3	0

[1] Safety Analysis Set

Baseline Characteristics

Analysis Population Description

Full Analysis Set defined as all randomized participants (as randomized) who received at least one dose of double-blind study medication, who have a non-missing baseline value and at least one post-baseline efficacy value for at least one efficacy variable during double-blind treatment period.

Reporting Groups

	Description
Dapagliflozin 2.5mg + Glimepiride	Dapagliflozin tablet 2.5 mg once daily plus glimepiride
Dapagliflozin 5mg + Glimepiride	Dapagliflozin tablet 5 mg once daily plus glimepiride
Dapagliflozin 10mg + Glimepiride	Dapagliflozin tablet 10 mg once daily plus glimepiride
Placebo + Glimepiride	Placebo comparator plus glimepiride

Baseline Measures

	Dapagliflozin 2.5mg + Glimepiride	Dapagliflozin 5mg + Glimepiride	Dapagliflozin 10mg + Glimepiride	Placebo + Glimepiride	Total
Number of Participants	154	142	151	145	592
Age, Continuous [units: years] Mean (Standard Deviation)	59.9 (10.14)	60.2 (9.73)	58.9 (8.32)	60.3 (10.16)	59.8 (9.60)
Gender, Male/Female [units: Participants]					
Female	77	71	85	74	307
Male	77	71	66	71	285
Race/Ethnicity, Customized [units: Participants]					
White	108	96	106	101	411
Asian	46	46	45	44	181
BMI [units: kg/m2] Mean (Standard Deviation)	30.01 (5.120)	29.84 (5.182)	29.75 (5.641)	29.74 (4.569)	29.84 (5.135)
HbA1c [units: Percent] Mean (Standard Deviation)	8.11 (0.749)	8.12 (0.781)	8.07 (0.790)	8.15 (0.736)	8.11 (0.763)

Outcome Measures

1. Primary Outcome Measure:

Measure Title	Adjusted Mean Change in HbA1c Levels
Measure Description	To assess the efficacy of dapagliflozin compared to placebo as add-on therapy to glimepiride in improving glycemic control in participants with type 2 diabetes, as determined by the change in HbA1C levels from baseline to the end of the 24-week double-blind treatment period.
Time Frame	Baseline to Week 24
Safety Issue?	No

Analysis Population Description

Full Analysis Set, participants with non-missing baseline and Week 24 (LOCF) values

Reporting Groups

	Description
Dapagliflozin 2.5mg + Glimepiride	Dapagliflozin tablet 2.5 mg once daily plus glimepiride
Dapagliflozin 5mg + Glimepiride	Dapagliflozin tablet 5 mg once daily plus glimepiride
Dapagliflozin 10mg + Glimepiride	Dapagliflozin tablet 2.5 mg once daily plus glimepiride
Placebo + Glimepiride	Placebo comparator plus glimepiride

Measured Values

	Dapagliflozin 2.5mg + Glimepiride	Dapagliflozin 5mg + Glimepiride	Dapagliflozin 10mg + Glimepiride	Placebo + Glimepiride
Number of Participants Analyzed	154	142	150	143
Adjusted Mean Change in HbA1c Levels [units: Percent] Least Squares Mean (95% Confidence Interval)	-0.58 (-0.69 to -0.46)	-0.63 (-0.75 to -0.50)	-0.82 (-0.94 to -0.70)	-0.13 (-0.26 to -0.01)

Statistical Analysis 1 for Adjusted Mean Change in HbA1c Levels

Statistical Analysis Overview	Comparison Groups	Dapagliflozin 2.5mg + Glimepiride, Placebo + Glimepiride
	Comments	The null hypothesis is given as H0: mean(treat) minus mean(placebo) = 0 versus HA: mean(treat) minus mean(placebo) =/= 0 (with alpha = 0.019 applying Dunnett's adjustment, two-sided)

	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	<0.0001
	Comments	significant at alpha=0.019 (2-sided) applying Dunnett's adjustment. A hierarchical closed testing procedure was used to control the Type I error rate across the primary and key secondary endpoints.
	Method	ANCOVA
	Comments	with treatment group as effect (all treatment groups included) and baseline value as covariate.

Method of Estimation	Estimation Parameter	Mean Difference (Final Values)
	Estimated Value	-0.44
	Confidence Interval	(2-Sided) 95% -0.61 to -0.27
	Parameter Dispersion	Type: Standard Error of the mean Value: 0.0867
	Estimation Comments	[Not specified]

Statistical Analysis 2 for Adjusted Mean Change in HbA1c Levels

Statistical Analysis Overview	Comparison Groups	Dapagliflozin 5mg + Glimepiride, Placebo + Glimepiride
	Comments	The null hypothesis is given as H0: mean(treat) minus mean(placebo) = 0 versus HA: mean(treat) minus mean(placebo) =/= 0 (with alpha = 0.019 applying Dunnett's adjustment, two-sided).
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	<0.0001
	Comments	significant at alpha=0.019 (2-sided) applying Dunnett's adjustment. A hierarchical closed testing procedure was used to control the Type I error rate across the primary and key secondary endpoints.
	Method	ANCOVA
	Comments	with treatment group as effect (all treatment groups included) and baseline value as covariate.

Method of Estimation	Estimation Parameter	Mean Difference (Final Values)
	Estimated Value	-0.49
	Confidence Interval	(2-Sided) 95% -0.67 to -0.32
	Parameter Dispersion	Type: Standard Error of the mean Value: 0.0885
	Estimation Comments	[Not specified]

Statistical Analysis 3 for Adjusted Mean Change in HbA1c Levels

Statistical Analysis Overview	Comparison Groups	Dapagliflozin 10mg + Glimepiride, Placebo + Glimepiride
	Comments	The null hypothesis is given as H0: mean(treat) minus mean(placebo) = 0 versus HA: mean(treat) minus mean(placebo) =/= 0 (with alpha = 0.019 applying Dunnett's adjustment, two-sided).
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	<0.0001
	Comments	significant at alpha=0.019 (2-sided) applying Dunnett's adjustment. A hierarchical closed testing procedure was used to control the Type I error rate across the primary and key secondary endpoints.
	Method	ANCOVA
	Comments	with treatment group as effect (all treatment groups included) and baseline value as covariate.

Method of Estimation	Estimation Parameter	Mean Difference (Final Values)
	Estimated Value	-0.68
	Confidence Interval	(2-Sided) 95% -0.86 to -0.51
	Parameter Dispersion	Type: Standard Error of the mean Value: 0.0873
	Estimation Comments	[Not specified]

2. Secondary Outcome Measure:

Measure Title	Adjusted Mean Change in Body Weight
Measure Description	To show that dapagliflozin plus glimepiride results in greater reduction in body weight or less weight gain after 24 weeks of treatment when compared to placebo plus glimepiride.
Time Frame	Baseline to Week 24
Safety Issue?	No

Analysis Population Description

Full Analysis Set, participants with non-missing baseline and Week 24 (LOCF) values

Reporting Groups

	Description
Dapagliflozin 2.5mg + Glimepiride	Dapagliflozin tablet 2.5 mg once daily plus glimepiride
Dapagliflozin 5mg + Glimepiride	Dapagliflozin tablet 5 mg once daily plus glimepiride
Dapagliflozin 10mg + Glimepiride	Dapagliflozin tablet 10 mg once daily plus glimepiride
Placebo + Glimepiride	Placebo comparator plus glimepiride

Measured Values

	Dapagliflozin 2.5mg + Glimepiride	Dapagliflozin 5mg + Glimepiride	Dapagliflozin 10mg + Glimepiride	Placebo + Glimepiride
Number of Participants Analyzed	154	142	151	145
Adjusted Mean Change in Body Weight [units: kg] Least Squares Mean (95% Confidence Interval)	-1.18 (-1.62 to -0.75)	-1.56 (-2.01 to -1.11)	-2.26 (-2.70 to -1.83)	-0.72 (-1.16 to -0.28)

Statistical Analysis 1 for Adjusted Mean Change in Body Weight

Statistical Analysis Overview	Comparison Groups	Dapagliflozin 2.5mg + Glimepiride, Placebo + Glimepiride
	Comments	The null hypothesis is given as H0: mean(treat) minus mean(placebo) = 0 versus HA: mean(treat) minus mean(placebo) =/= 0
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.1410
	Comments	not significant at alpha=0.05 (2-sided). Primary and key secondary endpoints are tested following a hierarchical closed testing procedure within treatment group.
	Method	ANCOVA
	Comments	with treatment group as effect (all treatment groups included) and baseline value as covariate.

Method of Estimation	Estimation Parameter	Mean Difference (Final Values)
	Estimated Value	-0.46
	Confidence Interval	(2-Sided) 95% -1.08 to 0.15
	Parameter Dispersion	Type: Standard Error of the mean Value: 0.3153
	Estimation Comments	[Not specified]

Statistical Analysis 2 for Adjusted Mean Change in Body Weight

Statistical Analysis Overview	Comparison Groups	Dapagliflozin 5mg + Glimepiride, Placebo + Glimepiride
	Comments	The null hypothesis is given as H0: mean(treat) minus mean(placebo) = 0 versus HA: mean(treat) minus mean(placebo) =/= 0
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.0091
	Comments	significant at alpha=0.05 (2-sided). Primary and key secondary endpoints are tested following a hierarchical closed testing procedure within treatment group.
	Method	ANCOVA
	Comments	with treatment group as effect (all treatment groups included) and baseline value as covariate.

Method of Estimation	Estimation Parameter	Mean Difference (Final Values)
	Estimated Value	-0.84
	Confidence Interval	(2-Sided) 95% -1.47 to -0.21
	Parameter Dispersion	Type: Standard Error of the mean

		Value: 0.3217
	Estimation Comments	[Not specified]

Statistical Analysis 3 for Adjusted Mean Change in Body Weight

Statistical Analysis Overview	Comparison Groups	Dapagliflozin 10mg + Glimepiride, Placebo + Glimepiride
	Comments	The null hypothesis is given as H0: mean(treat) minus mean(placebo) = 0 versus HA: mean(treat) minus mean(placebo) =/= 0
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	<0.0001
	Comments	significant at alpha=0.05 (2-sided). Primary and key secondary endpoints are tested following a hierarchical closed testing procedure within treatment group.
	Method	ANCOVA
	Comments	with treatment group as effect (all treatment groups included) and baseline value as covariate.

Method of Estimation	Estimation Parameter	Mean Difference (Final Values)
	Estimated Value	-1.54
	Confidence Interval	(2-Sided) 95% -2.17 to -0.92
	Parameter Dispersion	Type: Standard Error of the mean Value: 0.3168
	Estimation Comments	[Not specified]

3. Secondary Outcome Measure:

Measure Title	Adjusted Mean Change in 2-h Post-challenge Plasma Glucose Rise
Measure Description	To show that dapagliflozin plus glimepiride results in greater reductions in the 2-h post-challenge plasma glucose rise as a response to an oral glucose tolerance test (OGTT) from baseline to Week 24.
Time Frame	Baseline to Week 24
Safety Issue?	No

Analysis Population Description

Full Analysis Set, participants with non-missing baseline and Week 24 (LOCF) values

Reporting Groups

	Description
Dapagliflozin 2.5mg + Glimepiride	Dapagliflozin tablet 2.5 mg once daily plus glimepiride
Dapagliflozin 5mg + Glimepiride	Dapagliflozin tablet 5 mg once daily plus glimepiride
Dapagliflozin 10mg + Glimepiride	Dapagliflozin tablet 10 mg once daily plus glimepiride
Placebo + Glimepiride	Placebo comparator plus glimepiride

Measured Values

	Dapagliflozin 2.5mg + Glimepiride	Dapagliflozin 5mg + Glimepiride	Dapagliflozin 10mg + Glimepiride	Placebo + Glimepiride
Number of Participants Analyzed	126	117	132	109
Adjusted Mean Change in 2-h Post-challenge Plasma Glucose Rise [units: mg/dL] Least Squares Mean (95% Confidence Interval)	-37.5 (-46.7 to -28.3)	-32.0 (-41.5 to -22.5)	-34.9 (-43.8 to -25.9)	-6.0 (-15.8 to 3.9)

Statistical Analysis 1 for Adjusted Mean Change in 2-h Post-challenge Plasma Glucose Rise

Statistical Analysis Overview	Comparison Groups	Dapagliflozin 2.5mg + Glimepiride, Placebo + Glimepiride
	Comments	The null hypothesis is given as H0: mean(treat) minus mean(placebo) = 0 versus HA: mean(treat) minus mean(placebo) =/= 0
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	
	Comments	Not significant. Hierarchical closed testing procedure within treatment group stopped at previous endpoint.
	Method	ANCOVA
	Comments	with treatment group as effect (all treatment groups included) and baseline value as covariate.

Method of Estimation	Estimation Parameter	Mean Difference (Final Values)
	Estimated Value	-31.5

	Confidence Interval	(2-Sided) 95% -45.0 to -18.0
	Parameter Dispersion	Type: Standard Error of the mean Value: 6.874
	Estimation Comments	[Not specified]

Statistical Analysis 2 for Adjusted Mean Change in 2-h Post-challenge Plasma Glucose Rise

Statistical Analysis Overview	Comparison Groups	Dapagliflozin 5mg + Glimepiride, Placebo + Glimepiride
	Comments	The null hypothesis is given as H0: mean(treat) minus mean(placebo) = 0 versus HA: mean(treat) minus mean(placebo) =/= 0
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.0002
	Comments	significant at alpha=0.05 (2-sided). Primary and key secondary endpoints are tested following a hierarchical closed testing procedure within treatment group.
	Method	ANCOVA
	Comments	with treatment group as effect (all treatment groups included) and baseline value as covariate.

Method of Estimation	Estimation Parameter	Mean Difference (Final Values)
	Estimated Value	-26.0
	Confidence Interval	(2-Sided) 95% -39.7 to -12.3
	Parameter Dispersion	Type: Standard Error of the mean Value: 6.968
	Estimation Comments	[Not specified]

Statistical Analysis 3 for Adjusted Mean Change in 2-h Post-challenge Plasma Glucose Rise

Statistical Analysis Overview	Comparison Groups	Dapagliflozin 10mg + Glimepiride, Placebo + Glimepiride
	Comments	The null hypothesis is given as H0: mean(treat) minus mean(placebo) = 0 versus HA: mean(treat) minus mean(placebo) =/= 0
	Non-Inferiority or Equivalence Analysis?	No

	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	<0.0001
	Comments	significant at alpha=0.05 (2-sided). Primary and key secondary endpoints are tested following a hierarchical closed testing procedure within treatment group.
	Method	ANCOVA
	Comments	with treatment group as effect (all treatment groups included) and baseline value as covariate.

Method of Estimation	Estimation Parameter	Mean Difference (Final Values)
	Estimated Value	-28.9
	Confidence Interval	(2-Sided) 95% -42.2 to -15.6
	Parameter Dispersion	Type: Standard Error of the mean Value: 6.770
	Estimation Comments	[Not specified]

4. Secondary Outcome Measure:

Measure Title	Proportion of Participants Achieving Glycemic Response Defined as HbA1c <7%
Measure Description	To show that dapagliflozin plus glimepiride results in a larger proportion of participants achieving a therapeutic glycemic response, defined as HbA1c < 7% after 24 weeks of treatment, compared to placebo plus glimepiride.
Time Frame	At Week 24
Safety Issue?	No

Analysis Population Description

Full Analysis Set, participants with non-missing baseline and Week 24 (LOCF) values

Reporting Groups

	Description
Dapagliflozin 2.5mg + Glimepiride	Dapagliflozin tablet 2.5 mg once daily plus glimepiride
Dapagliflozin 5mg + Glimepiride	Dapagliflozin tablet 5 mg once daily plus glimepiride
Dapagliflozin 10mg + Glimepiride	Dapagliflozin tablet 10 mg once daily plus glimepiride
Placebo + Glimepiride	Placebo comparator plus glimepiride

Measured Values

	Dapagliflozin 2.5mg + Glimepiride	Dapagliflozin 5mg + Glimepiride	Dapagliflozin 10mg + Glimepiride	Placebo + Glimepiride
Number of Participants Analyzed	154	142	150	143
Proportion of Participants Achieving Glycemic Response Defined as HbA1c <7% [units: Percentage of participants] Least Squares Mean (95% Confidence Interval)	26.8 (20.2 to 33.3)	30.3 (23.4 to 37.1)	31.7 (24.7 to 38.7)	13.0 (7.6 to 18.4)

Statistical Analysis 1 for Proportion of Participants Achieving Glycemic Response Defined as HbA1c <7%

Statistical Analysis Overview	Comparison Groups	Dapagliflozin 2.5mg + Glimepiride, Placebo + Glimepiride
	Comments	H0: proportion(treat) minus proportion(placebo) = 0 versus the alternative HA: proportion(treat) minus proportion(placebo) =/= 0
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	
	Comments	Not significant. Hierarchical closed testing procedure within treatment group stopped at previous endpoint.
	Method	Regression, Logistic
	Comments	Based on methodology of Zhang, Tsiatis & Davidian and Davidian, Tsiatis, Zhang & Lu, with adjustment for baseline value.

Method of Estimation	Estimation Parameter	Risk Difference (RD)
	Estimated Value	13.7
	Confidence Interval	(2-Sided) 95% 5.4 to 22.1
	Parameter Dispersion	Type: Standard Error of the mean Value: 4.265
	Estimation Comments	[Not specified]

Statistical Analysis 2 for Proportion of Participants Achieving Glycemic Response Defined as HbA1c <7%

Statistical Analysis Overview	Comparison Groups	Dapagliflozin 5mg + Glimepiride, Placebo + Glimepiride
	Comments	H0: proportion(treat) minus proportion(placebo) = 0 versus the alternative HA: proportion(treat) minus proportion(placebo) =/= 0
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.0001
	Comments	significant at alpha=0.05 (2-sided). Primary and key secondary endpoints are tested following a hierarchical closed testing procedure within treatment group.
	Method	Regression, Logistic
	Comments	Based on methodology of Zhang, Tsiatis & Davidian and Davidian, Tsiatis, Zhang & Lu, with adjustment for baseline value.

Method of Estimation	Estimation Parameter	Risk Difference (RD)
	Estimated Value	17.3
	Confidence Interval	(2-Sided) 95% 8.7 to 25.9
	Parameter Dispersion	Type: Standard Error of the mean Value: 4.392
	Estimation Comments	[Not specified]

Statistical Analysis 3 for Proportion of Participants Achieving Glycemic Response Defined as HbA1c <7%

Statistical Analysis Overview	Comparison Groups	Dapagliflozin 10mg + Glimepiride, Placebo + Glimepiride
	Comments	H0: proportion(treat) minus proportion(placebo) = 0 versus the alternative HA: proportion(treat) minus proportion(placebo) =/= 0
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	<0.0001
	Comments	significant at alpha=0.05 (2-sided). Primary and key secondary endpoints are tested following a hierarchical closed testing procedure within treatment group.
	Method	Regression, Logistic

	Comments	Based on methodology of Zhang, Tsiatis & Davidian and Davidian, Tsiatis, Zhang & Lu, with adjustment for baseline value.

Method of Estimation	Estimation Parameter	Risk Difference (RD)
	Estimated Value	18.7
	Confidence Interval	(2-Sided) 95% 9.9 to 27.4
	Parameter Dispersion	Type: Standard Error of the mean Value: 4.457
	Estimation Comments	[Not specified]

5. Secondary Outcome Measure:

Measure Title	Adjusted Mean Change in Body Weight for Participants With Baseline Body Mass Index (BMI)≥27 kg/m2
Measure Description	To show that dapagliflozin plus glimepiride results in greater reductions in body weight or less weight gain in participants with baseline BMI ≥27 kg/m2 after 24 weeks of treatment when compared to placebo plus glimepiride.
Time Frame	Baseline to Week 24
Safety Issue?	No

Analysis Population Description

Full Analysis Set, participants with baseline BMI of 27 kg/m2 or more and Week 24 (LOCF) body weight value

Reporting Groups

	Description
Dapagliflozin 2.5mg + Glimepiride	Dapagliflozin tablet 2.5 mg once daily plus glimepiride
Dapagliflozin 5mg + Glimepiride	Dapagliflozin tablet 5 mg once daily plus glimepiride
Dapagliflozin 10mg + Glimepiride	Dapagliflozin tablet 10 mg once daily plus glimepiride
Placebo + Glimepiride	Placebo comparator plus glimepiride

Measured Values

	Dapagliflozin 2.5mg + Glimepiride	Dapagliflozin 5mg + Glimepiride	Dapagliflozin 10mg + Glimepiride	Placebo + Glimepiride
Number of Participants Analyzed	104	97	99	103
Adjusted Mean Change in Body Weight for Participants With Baseline Body Mass Index (BMI)≥27 kg/m2	-1.17 (-1.75 to -0.59)	-1.74 (-2.34 to -1.15)	-2.47 (-3.06 to -1.88)	-0.80 (-1.38 to -0.22)

	Dapagliflozin 2.5mg + Glimepiride	Dapagliflozin 5mg + Glimepiride	Dapagliflozin 10mg + Glimepiride	Placebo + Glimepiride
[units: kg] Least Squares Mean (95% Confidence Interval)				

Statistical Analysis 1 for Adjusted Mean Change in Body Weight for Participants With Baseline Body Mass Index (BMI)≥27 kg/m2

Statistical Analysis Overview	Comparison Groups	Dapagliflozin 2.5mg + Glimepiride, Placebo + Glimepiride
	Comments	The null hypothesis is given as H0: mean(treat) minus mean(placebo) = 0 versus HA: mean(treat) minus mean(placebo) =/= 0
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	
	Comments	Not significant. Hierarchical closed testing procedure within treatment group stopped at previous endpoint.
	Method	ANCOVA
	Comments	with treatment group as effect (all treatment groups included) and baseline value as covariate.

Method of Estimation	Estimation Parameter	Mean Difference (Final Values)
	Estimated Value	-0.37
	Confidence Interval	(2-Sided) 95% -1.19 to 0.45
	Parameter Dispersion	Type: Standard Error of the mean Value: 0.4159
	Estimation Comments	[Not specified]

Statistical Analysis 2 for Adjusted Mean Change in Body Weight for Participants With Baseline Body Mass Index (BMI)≥27 kg/m2

Statistical Analysis Overview	Comparison Groups	Dapagliflozin 5mg + Glimepiride, Placebo + Glimepiride
	Comments	The null hypothesis is given as H0: mean(treat) minus mean(placebo) = 0 versus HA: mean(treat) minus mean(placebo) =/= 0
	Non-Inferiority or Equivalence Analysis?	No

	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.0262
	Comments	significant at alpha=0.05 (2-sided). Primary and key secondary endpoints are tested following a hierarchical closed testing procedure within treatment group.
	Method	ANCOVA
	Comments	with treatment group as effect (all treatment groups included) and baseline value as covariate.

Method of Estimation	Estimation Parameter	Mean Difference (Final Values)
	Estimated Value	-0.94
	Confidence Interval	(2-Sided) 95% -1.78 to -0.11
	Parameter Dispersion	Type: Standard Error of the mean Value: 0.4234
	Estimation Comments	[Not specified]

Statistical Analysis 3 for Adjusted Mean Change in Body Weight for Participants With Baseline Body Mass Index (BMI)≥27 kg/m2

Statistical Analysis Overview	Comparison Groups	Dapagliflozin 10mg + Glimepiride, Placebo + Glimepiride
	Comments	The null hypothesis is given as H0: mean(treat) minus mean(placebo) = 0 versus HA: mean(treat) minus mean(placebo) =/= 0
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	<0.0001
	Comments	significant at alpha=0.05 (2-sided). Primary and key secondary endpoints are tested following a hierarchical closed testing procedure within treatment group.
	Method	ANCOVA
	Comments	with treatment group as effect (all treatment groups included) and baseline value as covariate.

Method of Estimation	Estimation Parameter	Mean Difference (Final Values)
	Estimated Value	-1.67
	Confidence Interval	(2-Sided) 98%

		-2.50 to -0.84
	Parameter Dispersion	Type: Standard Error of the mean Value: 0.4211
	Estimation Comments	[Not specified]

6. Secondary Outcome Measure:

Measure Title	Adjusted Mean Change in Fasting Plasma Glucose (FPG)
Measure Description	To show that dapagliflozin plus glimepiride leads to greater reductions in FPG after 24 weeks of treatment compared to placebo plus glimepiride.
Time Frame	Baseline to Week 24
Safety Issue?	No

Analysis Population Description

Full Analysis Set, participants with non-missing baseline and Week 24 (LOCF) values

Reporting Groups

	Description
Dapagliflozin 2.5mg + Glimepiride	Dapagliflozin tablet 2.5 mg once daily plus glimepiride
Dapagliflozin 5mg + Glimepiride	Dapagliflozin tablet 5 mg once daily plus glimepiride
Dapagliflozin 10mg + Glimepiride	Dapagliflozin tablet 10 mg once daily plus glimepiride
Placebo + Glimepiride	Placebo comparator plus glimepiride

Measured Values

	Dapagliflozin 2.5mg + Glimepiride	Dapagliflozin 5mg + Glimepiride	Dapagliflozin 10mg + Glimepiride	Placebo + Glimepiride
Number of Participants Analyzed	154	142	150	145
Adjusted Mean Change in Fasting Plasma Glucose (FPG) [units: mg/dL] Least Squares Mean (95% Confidence Interval)	-16.8 (-21.7 to -12.0)	-21.2 (-26.3 to -16.2)	-28.5 (-33.4 to -23.6)	-2.0 (-6.9 to 3.0)

Statistical Analysis 1 for Adjusted Mean Change in Fasting Plasma Glucose (FPG)

Statistical Analysis Overview	Comparison Groups	Dapagliflozin 2.5mg + Glimepiride, Placebo + Glimepiride
	Comments	The null hypothesis is given as H0: mean(treat) minus mean(placebo) = 0 versus HA: mean(treat) minus mean(placebo) =/= 0
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	
	Comments	Not significant. Hierarchical closed testing procedure within treatment group stopped at previous endpoint.
	Method	ANCOVA
	Comments	with treatment group as effect (all treatment groups included) and baseline value as covariate.

Method of Estimation	Estimation Parameter	Mean Difference (Final Values)
	Estimated Value	-14.9
	Confidence Interval	(2-Sided) 95% -21.8 to -7.9
	Parameter Dispersion	Type: Standard Error of the mean Value: 3.522
	Estimation Comments	[Not specified]

Statistical Analysis 2 for Adjusted Mean Change in Fasting Plasma Glucose (FPG)

Statistical Analysis Overview	Comparison Groups	Dapagliflozin 5mg + Glimepiride, Placebo + Glimepiride
	Comments	The null hypothesis is given as H0: mean(treat) minus mean(placebo) = 0 versus HA: mean(treat) minus mean(placebo) =/= 0
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	<0.0001
	Comments	significant at alpha=0.05 (2-sided). Primary and key secondary endpoints are tested following a hierarchical closed testing procedure within treatment group.
	Method	ANCOVA

	Comments	with treatment group as effect (all treatment groups included) and baseline value as covariate.

Method of Estimation	Estimation Parameter	Mean Difference (Final Values)
	Estimated Value	-19.3
	Confidence Interval	(2-Sided) 95% -26.3 to -12.2
	Parameter Dispersion	Type: Standard Error of the mean Value: 3.594
	Estimation Comments	[Not specified]

Statistical Analysis 3 for Adjusted Mean Change in Fasting Plasma Glucose (FPG)

Statistical Analysis Overview	Comparison Groups	Dapagliflozin 10mg + Glimepiride, Placebo + Glimepiride
	Comments	The null hypothesis is given as H0: mean(treat) minus mean(placebo) = 0 versus HA: mean(treat) minus mean(placebo) =/= 0
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	<0.0001
	Comments	significant at alpha=0.05 (2-sided). Primary and key secondary endpoints are tested following a hierarchical closed testing procedure within treatment group.
	Method	ANCOVA
	Comments	with treatment group as effect (all treatment groups included) and baseline value as covariate.

Method of Estimation	Estimation Parameter	Mean Difference (Final Values)
	Estimated Value	-26.5
	Confidence Interval	(2-Sided) 95% -33.5 to -19.5
	Parameter Dispersion	Type: Standard Error of the mean Value: 3.545
	Estimation Comments	[Not specified]

Reported Adverse Events

Time Frame	Non-serious/serious adverse events on or after the first day and on or prior to the last day of the 24-week double-blind treatment period plus 4/30 days or up to follow-up visit if earlier, or up to and incl the start date of extension period if earlier.
Additional Description	Participants were questioned at each study visit about the occurrence of any health problems and any examination conducted at a study visit was assessed in comparison to the status at study entry.

Reporting Groups

	Description
Dapagliflozin 2.5mg + Glimepiride	Dapagliflozin tablet 2.5 mg once daily plus glimepiride
Dapagliflozin 5mg + Glimepiride	Dapagliflozin tablet 5 mg once daily plus glimepiride
Dapagliflozin 10mg + Glimepiride	Dapagliflozin tablet 10 mg once daily plus glimepiride
Placebo + Glimepiride	Placebo comparator plus glimepiride

Serious Adverse Events

	Dapagliflozin 2.5mg + Glimepiride	Dapagliflozin 5mg + Glimepiride	Dapagliflozin 10mg + Glimepiride	Placebo + Glimepiride
	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)
Total	11/154 (7.14%)	10/145 (6.9%)	9/151 (5.96%)	7/146 (4.79%)
Blood and lymphatic system disorders				
Febrile Neutropenia [A] †	1/154 (0.65%)	0/145 (0%)	0/151 (0%)	0/146 (0%)
Cardiac disorders				
ACUTE MYOCARDIAL INFARCTION [A] †	0/154 (0%)	0/145 (0%)	0/151 (0%)	1/146 (0.68%)
ANGINA PECTORIS [A] †	1/154 (0.65%)	1/145 (0.69%)	0/151 (0%)	0/146 (0%)
ANGINA UNSTABLE [A] †	1/154 (0.65%)	0/145 (0%)	0/151 (0%)	0/146 (0%)
AORTIC VALVE DISEASE MIXED [A] †	0/154 (0%)	0/145 (0%)	0/151 (0%)	1/146 (0.68%)
ATRIOVENTRICULAR BLOCK COMPLETE [A] †	0/154 (0%)	0/145 (0%)	1/151 (0.66%)	0/146 (0%)
CARDIAC FAILURE [A] †	0/154 (0%)	0/145 (0%)	0/151 (0%)	1/146 (0.68%)

	Dapagliflozin 2.5mg + Glimepiride	Dapagliflozin 5mg + Glimepiride	Dapagliflozin 10mg + Glimepiride	Placebo + Glimepiride
	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)
CARDIO-RESPIRATORY ARREST [A] †	1/154 (0.65%)	0/145 (0%)	0/151 (0%)	0/146 (0%)
CORONARY ARTERY DISEASE [A] †	0/154 (0%)	1/145 (0.69%)	0/151 (0%)	0/146 (0%)
CORONARY ARTERY STENOSIS [A] †	0/154 (0%)	0/145 (0%)	0/151 (0%)	1/146 (0.68%)
SUPRAVENTRICULAR TACHYCARDIA [A] †	0/154 (0%)	0/145 (0%)	1/151 (0.66%)	0/146 (0%)
Ear and labyrinth disorders				
VERTIGO [A] †	0/154 (0%)	1/145 (0.69%)	0/151 (0%)	0/146 (0%)
Gastrointestinal disorders				
GASTRODUODENITIS [A] †	1/154 (0.65%)	0/145 (0%)	0/151 (0%)	0/146 (0%)
General disorders				
NON-CARDIAC CHEST PAIN [A] †	0/154 (0%)	0/145 (0%)	0/151 (0%)	1/146 (0.68%)
Hepatobiliary disorders				
CHOLECYSTITIS ACUTE [A] †	1/154 (0.65%)	0/145 (0%)	0/151 (0%)	0/146 (0%)
CHOLELITHIASIS [A] †	1/154 (0.65%)	0/145 (0%)	0/151 (0%)	0/146 (0%)
Immune system disorders				
MULTIPLE ALLERGIES [A] †	1/154 (0.65%)	0/145 (0%)	0/151 (0%)	0/146 (0%)
Infections and infestations				
PNEUMONIA [A] †	1/154 (0.65%)	0/145 (0%)	2/151 (1.32%)	0/146 (0%)
Injury, poisoning and procedural complications				
HAND FRACTURE [A] †	0/154 (0%)	0/145 (0%)	0/151 (0%)	1/146 (0.68%)
JOINT DISLOCATION [A] †	0/154 (0%)	0/145 (0%)	1/151 (0.66%)	0/146 (0%)
OVERDOSE [A] †	1/154 (0.65%)	0/145 (0%)	1/151 (0.66%)	0/146 (0%)
Metabolism and nutrition disorders				
DIABETES MELLITUS [A] †	0/154 (0%)	2/145 (1.38%)	0/151 (0%)	0/146 (0%)

	Dapagliflozin 2.5mg + Glimepiride	Dapagliflozin 5mg + Glimepiride	Dapagliflozin 10mg + Glimepiride	Placebo + Glimepiride
	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)
OBESITY [A] †	0/154 (0%)	0/145 (0%)	0/151 (0%)	1/146 (0.68%)
Musculoskeletal and connective tissue disorders				
ARTHRITIS [A] †	0/154 (0%)	1/145 (0.69%)	0/151 (0%)	0/146 (0%)
BACK PAIN [A] †	0/154 (0%)	1/145 (0.69%)	0/151 (0%)	0/146 (0%)
NECK PAIN [A] †	0/154 (0%)	1/145 (0.69%)	0/151 (0%)	0/146 (0%)
ROTATOR CUFF SYNDROME [A] †	0/154 (0%)	1/145 (0.69%)	0/151 (0%)	0/146 (0%)
SPINAL COLUMN STENOSIS [A] †	1/154 (0.65%)	0/145 (0%)	0/151 (0%)	0/146 (0%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)				
BENIGN BREAST NEOPLASM [A] †	0/154 (0%)	1/145 (0.69%)	0/151 (0%)	0/146 (0%)
CHRONIC LYMPHOCYTIC LEUKAEMIA [A] †	1/154 (0.65%)	0/145 (0%)	0/151 (0%)	0/146 (0%)
LUNG NEOPLASM MALIGNANT [A] †	1/154 (0.65%)	0/145 (0%)	0/151 (0%)	0/146 (0%)
RECTAL ADENOMA [A] †	0/154 (0%)	1/145 (0.69%)	0/151 (0%)	1/146 (0.68%)
Nervous system disorders				
CEREBROVASCULAR ACCIDENT [A] †	0/154 (0%)	0/145 (0%)	1/151 (0.66%)	0/146 (0%)
TRANSIENT ISCHAEMIC ATTACK [A] †	1/154 (0.65%)	0/145 (0%)	0/151 (0%)	0/146 (0%)
Renal and urinary disorders				
RENAL COLIC [A] †	0/154 (0%)	0/145 (0%)	1/151 (0.66%)	0/146 (0%)
Reproductive system and breast disorders				
UTERINE POLYP [A] †	0/154 (0%)	0/145 (0%)	1/151 (0.66%)	0/146 (0%)
Respiratory, thoracic and mediastinal disorders				
PNEUMOTHORAX [A] †	0/154 (0%)	0/145 (0%)	0/151 (0%)	1/146 (0.68%)
PULMONARY EMBOLISM [A] †	0/154 (0%)	0/145 (0%)	1/151 (0.66%)	0/146 (0%)

	Dapagliflozin 2.5mg + Glimepiride	Dapagliflozin 5mg + Glimepiride	Dapagliflozin 10mg + Glimepiride	Placebo + Glimepiride
	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)
PULMONARY OEDEMA [A] †	0/154 (0%)	0/145 (0%)	0/151 (0%)	1/146 (0.68%)
Vascular disorders				
DEEP VEIN THROMBOSIS [A] †	0/154 (0%)	0/145 (0%)	1/151 (0.66%)	0/146 (0%)

† Indicates events were collected by systematic assessment.
A Term from vocabulary, MedDRA 12.1

Other Adverse Events

Frequency Threshold Above Which Other Adverse Events are Reported: 5%

	Dapagliflozin 2.5mg + Glimepiride	Dapagliflozin 5mg + Glimepiride	Dapagliflozin 10mg + Glimepiride	Placebo + Glimepiride
	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)
Total	22/154 (14.29%)	19/145 (13.1%)	18/151 (11.92%)	15/146 (10.27%)
Endocrine disorders				
Hypoglycemia [A] †	11/154 (7.14%)	10/145 (6.9%)	12/151 (7.95%)	7/146 (4.79%)
Infections and infestations				
NASOPHARYNGITIS [A] †	3/154 (1.95%)	8/145 (5.52%)	5/151 (3.31%)	4/146 (2.74%)
Vascular disorders				
HYPERTENSION [A] †	8/154 (5.19%)	2/145 (1.38%)	2/151 (1.32%)	6/146 (4.11%)

† Indicates events were collected by systematic assessment.
A Term from vocabulary, MedDRA 12.1

Limitations and Caveats

For participants who did not complete 24 weeks LOCF (last observation carried forward) was used. Only values prior to rescue medication were used.

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.

If an Investigator requests permission to publish data from this study any such publication is to be agreed with AstraZeneca (AZ) in advance. The investigator agrees to provide AZ as soon as possible with drafts of proposed publications. Unless otherwise agreed, AZ shall have a period of 60 days from receipt of the proposed final manuscript to review it and may within such time require that submission for publication of the manuscript be delayed in order for AZ to file patent applications.

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